

EXHIBIT 2

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

MDL No. 3036

3 : 22-md-03036-KDB

IN RE: GARDASIL PRODUCTS :

LIABILITY LITIGATION :

THIS DOCUMENT RELATES TO : ..

ALL ACTIONS

Videotaped deposition of
MARTIN KULLDORFF, Ph.D. taken at the offices of
Morgan & Morgan, 155 Federal Street, Suite 1502,
Boston, Massachusetts, before Clifford Edwards,
Certified Shorthand Reporter and Notary Public, in
and for the State of Connecticut on October 25,
2024, at 9:00 a.m. EDT.

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<p>1 APPEARANCES:</p> <p>2 (continued)</p> <p>3</p> <p>4 ALSO PRESENT:</p> <p>5 Robert Martignetti, videographer</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>Page 3</p> <p>1 EXHIBITS</p> <p>2 (continued)</p> <p>3</p> <p>4 EXHIBIT PAGE</p> <p>5 MK 13, Scheller 2015 Paper 104</p> <p>6 MK 14, Naleway Paper 104</p> <p>7 MK 15, Grimaldi-Bensouda 2017 Paper 104</p> <p>8 MK 16, Feiring Paper 105</p> <p>9 MK 17, Miranda Paper 105</p> <p>10 MK 18, Dr. Sukumaran's Paper Regarding</p> <p>11 HPV Vaccine Safety 106</p> <p>12 MK 19, Varricchio Paper 110</p> <p>13 MK 20, Shimabukuro 2015 Paper 126</p> <p>14 MK 21, November 2015 EMA PRAC Assessment</p> <p>15 Report 158</p> <p>16 MK 22, Rebecca Chandler Paper 164</p> <p>17 MK 23, European Medicines Agency PRAC PSUR</p> <p>18 Assessment Report, dated January 2017 168</p> <p>19 MK 24, Paper by Yih, 2021, American Journal</p> <p>20 of Epidemiology 174</p> <p>21 MK 25, Report From Danish Health and</p> <p>22 Medicines Authority for Consideration</p> <p>23 by the EMA and Rapporteurs 186</p> <p>24 MK 26, Merck Report Reviewed in Connection</p> <p>25 with the Article 20 Procedure 193</p>

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1	EXHIBITS	1 THE VIDEOGRAPHER: We are now on the
2	(continued)	2 record. My name is Robert Martignetti.
3		3 I'm the videographer for Golkow
4		4 Litigation Services. Today's date is
5 EXHIBIT	PAGE	5 October 25, 2024, and the time is
6 MK 27, Minutes and Responses to PRAC from		6 9:01 a.m.
7 the SAG Vaccines Meeting on HPV		7 This video deposition is being held
8 Vaccines (Article 20 Referral)	208	8 in Boston, Massachusetts, In Re:
9 MK 28, Article by Patricia Wodi	225	9 Gardasil Products Liability Litigation.
10 MK 29, Paper by Arana, 2017	213	10 The deponent is Martin Kulldorff, Ph.D.
11 MK 30, Paper by Tatang	232	11 Counsel's appearances will be noted
12 MK 31, Article by Slade, et al.	236	12 on the stenographic record. The court
13 MK 32, 2012 Article by Dr. Tomljenovic and		13 reporter is Cliff Edwards.
14 Dr. Shaw	239	14
15 MK 33, MK 33, Document Entitled "FDA		15
16 Information on Gardasil -- Presence		16
17 of DNA Fragments Expected,		17
18 No Safety Risk"	259	18
19 MK 34, Fukushima Paper	269	19
20 MK 35, Suzuki and Hokono Article	278	20
21 MK 36, Invoice	286	21
22 MK 37, New England Journal of Medicine		22
23 Article from Salmon	290	23
24		24
25		25
	Page 7	Page 9
1	EXHIBITS	1 MARTIN KULLDORFF, Ph.D.
2	(continued)	2 residing at 103 Lake View Drive, Ashford,
3		3 Connecticut, 06278, having first been duly sworn,
4		4 deposed and testified as follows:
5		5 THE COURT REPORTER: Thank you.
6		6 MR. TOMASELLI: Great.
7		7
8 (Reporter's Note: Original exhibits retained by the		8 DIRECT EXAMINATION
9 court reporter and forwarded to Golkow for		9
10 production.)		10 BY MR. TOMASELLI:
11		11 Q Dr. Kulldorff, my name is Joe Tomaselli.
12		12 And I just introduced myself to you a couple minutes
13		13 ago; right?
14		14 A Yup.
15		15 Q We've never met before; correct?
16		16 A We have not.
17		17 Q You understand that I represent Merck in
18		18 this case?
19		19 A Yes.
20		20 Q Okay. You understand that I'm here to
21		21 take your deposition?
22		22 A Yes.
23		23 Q Great.
24		24 Will you please state your full name?
25		25 A Martin Kulldorff.

3 (Pages 6 - 9)

<p style="text-align: right;">Page 10</p> <p>1 Q And where do you live? 2 A Ashford, Connecticut. 3 Q Born in 1962? 4 A Yes. 5 Q Have you ever been deposed before? 6 A Yes. 7 Q So you understand that the rules of a 8 deposition are that, if we can, we should try not to 9 talk over one another; okay? 10 A Okay. 11 Q And if you answer my question, I'll 12 assume that you understood it; okay? 13 A Okay. 14 Q You understand that Merck is one of the 15 manufacturers of an HPV vaccine that's distributed 16 worldwide? 17 A Yes. 18 Q How many other companies distribute HPV 19 vaccines? 20 A There's a company -- there's a vaccine 21 called Cervarix. 22 Q Are you aware of any others? 23 A No. 24 Q My understanding is that your primary 25 education was in Sweden; is that right?</p>	<p style="text-align: right;">Page 12</p> <p>1 graduate school in the U.S. 2 Q She went to what? 3 I'm sorry. 4 A Graduate school. 5 Q Graduate school? 6 A In the U.S. 7 Q And did you then work for the National 8 Cancer Institute? 9 A Yes. 10 Q And the National Cancer Institute is part 11 of the National Institutes of Health; correct? 12 A Yes. 13 Q A governmental agency for the United 14 States; right? 15 A Yes. 16 Q You said you've been deposed before in 17 litigation. 18 How many times? 19 A I believe one time. 20 Q One time? 21 A (The witness nods head.) 22 Q And can you tell me the nature of that 23 case? 24 A Family court. 25 Q You've never been deposed or offered</p>
<p style="text-align: right;">Page 11</p> <p>1 A I was educated both in Sweden and the 2 United States. 3 (Whereupon, the court reporter 4 requests clarification.) 5 THE WITNESS: I was educated both in 6 Sweden and the United States. 7 BY MR. TOMASELLI: 8 Q Right. 9 In 1984, you received your bachelor of 10 science in mathematics statistics from Umeå 11 University in Sweden? 12 A Yes. Umeå. 13 Q And that's U-m-e-a? 14 A U-m-e-å, with a circle over the "A." 15 Q Okay. And how do you say that? 16 A Umeå. 17 Q In 1989, you received your Ph.D. in 18 operations research from Cornell here in the United 19 States; correct? 20 A Yes. 21 Q You came to work in the United States for 22 good in about 1995; is that right? 23 A That sounds right -- about. 24 Q And what brought you here in 1995? 25 A My wife, at the time, went to go to</p>	<p style="text-align: right;">Page 13</p> <p>1 expert opinions in a case where a product is alleged 2 to cause an adverse event; right? 3 A Not before this one. 4 Q What I said was right? 5 A (The witness nods head.) 6 Q Yes? 7 A Yeah. I think you said before. Yeah. 8 Q You've never before -- 9 A Yes. Correct. 10 Q Okay. Sometimes I'll phrase something 11 one way, and -- and "yes" or "no" -- oftentimes, 12 "no" -- is hard to understand. 13 And so if I say what I said was correct 14 or if I ask you to say "yes," maybe you shook your 15 head or something like that on the record. 16 I'm not trying to be rude or -- or 17 anything. I just am trying to get a -- a transcript 18 that others can read later. 19 Okay? 20 A Okay. 21 Q Thank you. 22 We talked about the National Cancers 23 [sic] Institute and -- and the National Institutes 24 of Health. 25 Do you understand that part of their</p>

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<p style="text-align: right;">Page 14</p> <p>1 mission is to understand cancers and to prevent 2 cancers if they can?</p> <p>3 A Yes.</p> <p>4 Q You've been affiliated with Uppsala 5 University; is that right?</p> <p>6 A Yes.</p> <p>7 Q It's possible that it's pronounced some 8 other way.</p> <p>9 But if I say Uppsala, is that okay?</p> <p>10 A Good enough.</p> <p>11 Q Thank you.</p> <p>12 You've also been affiliated with Harvard 13 medicine -- Medical School; correct?</p> <p>14 A Yes.</p> <p>15 Q You were a professor of medicine from 16 approximately 2003 to 2021; right?</p> <p>17 A I was, first, an associate professor. 18 And then, I was a full processor.</p> <p>19 Q Fair enough.</p> <p>20 And you've also been associated with the 21 Brigham; right?</p> <p>22 A Correct.</p> <p>23 Q And the Brigham is a teaching institution 24 for Harvard; right?</p> <p>25 A Correct.</p>	<p style="text-align: right;">Page 16</p> <p>1 Q Okay. And was it over \$10,000?</p> <p>2 A I don't think so.</p> <p>3 Q Okay. And do you recall which products 4 that you advised the FDA on with respect to that 5 committee?</p> <p>6 A I cannot list them from the memory. No.</p> <p>7 Q Okay.</p> <p>8 A But there were a few different ones.</p> <p>9 Q Were any of them vaccines?</p> <p>10 A No.</p> <p>11 Q You were a member of the vaccine safety 12 subgroup of the advisory committee on immunization 13 practices at the Center for Disease Control; is that 14 right?</p> <p>15 A Do you mean that for the COVID vaccine?</p> <p>16 Q Well, let's start with you were a member 17 of the ACIP's -- strike that. Withdrawn.</p> <p>18 You were a member of the vaccine safety 19 group -- safety subgroup for the ACIP for the CDC in 20 approximately 2008 and 2009; is that right?</p> <p>21 A No.</p> <p>22 That's -- that's -- I was a member of 23 a -- a group around 2008 for -- specifically for one 24 vaccine; and then, around 2019, another different 25 working group for a different vaccine.</p>
<p style="text-align: right;">Page 15</p> <p>1 Q And my understanding is you were a 2 biostatistician for the Brigham from about 2015 to 3 2021; is that right?</p> <p>4 A I was a professor and a -- working as a 5 biostatistician.</p> <p>6 Q And are you still affiliated with Harvard 7 and the Brigham today?</p> <p>8 A No.</p> <p>9 Q And was that a voluntary choice on your 10 part?</p> <p>11 A No.</p> <p>12 Q My understanding is that you've worked 13 with the U.S. Food and Drug Administration's Drug 14 Safety and Risk Management Advisory Committee; is 15 that right?</p> <p>16 A Yes.</p> <p>17 Q From approximately 2018 to 2022; is that 18 right?</p> <p>19 A Sounds right.</p> <p>20 Q And was that a paid position?</p> <p>21 A There was an honoraria. But it's -- it's 22 small -- small.</p> <p>23 Q Okay. You were -- you were paid an 24 honoraria for your time in attending the meetings?</p> <p>25 A Yes.</p>	<p style="text-align: right;">Page 17</p> <p>1 Q When you --</p> <p>2 A And both were -- so sorry.</p> <p>3 Q I'm sorry. Go ahead.</p> <p>4 A Both were subgroups ad- -- advising the 5 ACIP.</p> <p>6 Q Fair enough.</p> <p>7 The vaccine that you were a member of the 8 subgroup on in 2008, what was that?</p> <p>9 A That was the MMRV, the measles, mumps, 10 rubella, varicella vaccine.</p> <p>11 Q And in 2019, what vaccine was that in 12 relation to?</p> <p>13 A That was all the COVID vaccines.</p> <p>14 Q All the COVID vaccines?</p> <p>15 A (The witness nods head.)</p> <p>16 Q And was your membership on the vaccine 17 safety subgroup a paid position; or, likewise, did 18 you receive a small honoraria for your time?</p> <p>19 A Neither was paid.</p> <p>20 Q Are subgroup members actually employees 21 of the CDC?</p> <p>22 A No.</p> <p>23 Q Are they generally from academic 24 institutions?</p> <p>25 A Some -- many academics, I think, and,</p>

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<p style="text-align: right;">Page 18</p> <p>1 sometimes, some hospitals. But there could be 2 others, also, in health -- like, health 3 insurance-plans-, HMOs-type things.</p> <p>4 Q The subgroup members are, generally, 5 experts in the field that they're asked to consult 6 on; is that right?</p> <p>7 A Yes.</p> <p>8 Q Have you ever been part of a subgroup or 9 a working group for HPV vaccines?</p> <p>10 A No.</p> <p>11 Q Do you know any of the individuals that 12 worked or consulted on a working group or subgroup 13 of the ACIP for HPV vaccines?</p> <p>14 A Who?</p> <p>15 Q I'm asking you if you know of any.</p> <p>16 A I know people who have sat on the ACIP, 17 and they may have had to deal with HPV vaccines. 18 But I don't really know who did what, when; so I 19 can't really answer that question. I don't know.</p> <p>20 Q Fair enough.</p> <p>21 My understanding is that you're 22 affiliated now with a group called Acumen, LLC; is 23 that right?</p> <p>24 A Yes.</p> <p>25 Q And that's been for the last couple</p>	<p style="text-align: right;">Page 20</p> <p>1 A I don't know.</p> <p>2 Q And it's true that you never suggested, 3 in your work for Acumen, that Gardasil was not safe 4 or efficacious; correct?</p> <p>5 A I have never discussed HPV vaccines with 6 them.</p> <p>7 Q So what I said was correct?</p> <p>8 You've never discussed it with them that 9 Gardasil -- well, withdrawn.</p> <p>10 You've never told anybody -- withdrawn.</p> <p>11 It's true that you've never suggested, in 12 your work for Acumen, that Gardasil was not safe or 13 efficacious?</p> <p>14 A I have not talked to them about Gardasil 15 in any -- any way in -- on any matter.</p> <p>16 Q Are you a medical doctor?</p> <p>17 A Nope.</p> <p>18 Q Do you hold yourself out as a physician?</p> <p>19 A No.</p> <p>20 Q Have you ever diagnosed, tested, or 21 treated a patient?</p> <p>22 A No.</p> <p>23 Unless you count my children that I 24 sometimes try to figure out what's going on -- 25 what's wrong with them.</p>
<p style="text-align: right;">Page 19</p> <p>1 years; is that right?</p> <p>2 A A- -- about. Yeah.</p> <p>3 Q I looked Acumen up, and it says that 4 they're an impartial, data-driven -- I'm sorry. 5 Withdrawn.</p> <p>6 I looked Acumen up. And it says that 7 they do impartial, data-driven analyses for 8 government agencies to help inform health care 9 decisions.</p> <p>10 Is that generally correct?</p> <p>11 A I think so.</p> <p>12 Q Does Acumen, LLC, try and promote the 13 public health in what y'all do today?</p> <p>14 A You'd have to ask them.</p> <p>15 Q Well, you're part of Acumen.</p> <p>16 Do you try to promote public health in 17 what you do?</p> <p>18 A Yes.</p> <p>19 Q In the medical product safety section for 20 Acumen, LLC, it says that they work with federal 21 agencies to monitor safety and efficacy of vaccines; 22 does that sound familiar?</p> <p>23 A That's part of what they do. Yeah.</p> <p>24 Q And does Acumen, LLC, work on, currently, 25 any HPV vaccines?</p>	<p style="text-align: right;">Page 21</p> <p>1 Q Just like any parent; right?</p> <p>2 A Exactly.</p> <p>3 Q And you've never diagnosed, tested, or 4 treated a patient with POTS, primary ovarian 5 insufficiency, chronic regional pain syndrome, 6 chronic fatigue syndrome, or fibromyalgia; right?</p> <p>7 A No, I haven't.</p> <p>8 Q When we talk about POTS, you understand 9 that I'm referring to postural orthostatic 10 tachycardia syndrome?</p> <p>11 A Yes.</p> <p>12 Q When we talk about POTS or primary 13 ovarian insufficiency or chronic regional pain 14 syndrome or chronic fatigue syndrome or fibromyalgia 15 today, you understand that those are medical 16 syndromes that are diagnosed by medical 17 professionals; right?</p> <p>18 A Yes.</p> <p>19 Q Have you ever been involved in assessing 20 individual cases in a chart review as part of a 21 epidemiologic study or a single-generation study?</p> <p>22 A No, I have not.</p> <p>23 Q If chart review was "porm" -- performed 24 as part of an epidemiologic study or chart -- 25 withdrawn.</p>

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<p style="text-align: right;">Page 22</p> <p>1 If chart review was performed as part of 2 an epidemiologic study or a signal generation study 3 that you were involved in, you would have deferred 4 to the physicians involved in that chart review; is 5 that fair?</p> <p>6 A Whoever is the PI would select the 7 physicians to do the short review.</p> <p>8 Q And as we discussed, that's never been 9 you; correct?</p> <p>10 A I have never been the one who selected 11 the short reviewers.</p> <p>12 Q Have you had any formal medical training 13 at all?</p> <p>14 A I have never had any formal training in 15 the -- like, for a physician or medicinal.</p> <p>16 Q In connection with this litigation that 17 we're having this deposition about, do you remember 18 who contacted you first?</p> <p>19 A From the company, it was, I believe, 20 Attorney Baum.</p> <p>21 Q And which company are you talking about?</p> <p>22 A Is it something-and-Baum?</p> <p>23 MR. BAUM: Wisner Baum.</p> <p>24 A Wisner Baum. Yeah. Sorry.</p> <p>25</p>	<p style="text-align: right;">Page 24</p> <p>1 consider yourself an expert in the safety of 2 Gardasil?</p> <p>3 A Yes.</p> <p>4 I don't know any -- everything about it, 5 but I know a lots. I would say I would be an expert 6 on it.</p> <p>7 Q Are you an expert in whether the 8 epidemiologic data available today shows that 9 Gardasil causes POTS or POI?</p> <p>10 A I have not read all the data, so I can't 11 give a definite view on that. And I haven't been 12 asked to do so as part of this litigation.</p> <p>13 Q Are you an expert in whether the 14 epidemiologic data available today shows that 15 Gardasil causes chronic fatigue syndrome or 16 fibromyalgia?</p> <p>17 A The same answer to that question.</p> <p>18 Q You charge \$400 an hour for your time; is 19 that right?</p> <p>20 A Yes.</p> <p>21 Q As of today, you have one invoice dated 22 October the 24th; is that right?</p> <p>23 A Yes.</p> <p>24 Q That was for time from June 27 through 25 September the 30th of 2024; correct?</p>
<p style="text-align: right;">Page 23</p> <p>1 BY MR. TOMASELLI:</p> <p>2 Q Just making sure that there wasn't some 3 other company that I didn't understand -- that I didn't 4 know about.</p> <p>5 So in connection with this litigation, 6 you were first contacted by Mr. Baum; right?</p> <p>7 A Yes.</p> <p>8 Q When was that?</p> <p>9 A In June.</p> <p>10 Q June of this year?</p> <p>11 A 2024.</p> <p>12 Q And do you know how Mr. Baum got your 13 name?</p> <p>14 A I think you should ask him that.</p> <p>15 Q Did you agree to work with Mr. Baum when 16 you were contacted in June of 2024?</p> <p>17 A I agreed in June. Yeah.</p> <p>18 Q Was it in connection with the first 19 conversation you had?</p> <p>20 A I think there were a few conversations 21 before it was agreed on. I don't remember exactly.</p> <p>22 Q Do you consider yourself an expert in the 23 safety of Gardasil?</p> <p>24 A I know a lot about that.</p> <p>25 Q Yeah. And my question is: Do you</p>	<p style="text-align: right;">Page 25</p> <p>1 A Yes.</p> <p>2 Q You charged approximately 82 hours during 3 that time period; is that right?</p> <p>4 A Yes.</p> <p>5 Q And your total invoice as of that invoice 6 is just at \$33,000; is that right?</p> <p>7 A Something around that number.</p> <p>8 Q You were paid a 4,000-dollar retainer; 9 correct?</p> <p>10 A Yes.</p> <p>11 Q Have you been paid for the balance of 12 that?</p> <p>13 A No.</p> <p>14 Q Do you expect to be paid for the balance 15 of that?</p> <p>16 A Yes.</p> <p>17 Q Do you know when?</p> <p>18 A No.</p> <p>19 Q How much more time have you put into this 20 case, if any, from September the 30th to today?</p> <p>21 A Maybe around 30 hours.</p> <p>22 Q And is that, again, at -- at \$400 an 23 hour?</p> <p>24 A Yes.</p> <p>25 Sorry.</p>

7 (Pages 22 - 25)

<p style="text-align: right;">Page 26</p> <p>1 Q No problem.</p> <p>2 In connection with your testimony today,</p> <p>3 will you be compensated for your time?</p> <p>4 A Yes. I believe so.</p> <p>5 Q And is it, again, at the rate of \$400 an</p> <p>6 hour?</p> <p>7 A Yes.</p> <p>8 Q Is it true that you've never been</p> <p>9 employed by a company that manufactures vaccines?</p> <p>10 A Correct.</p> <p>11 Q And is it true that you've never worked</p> <p>12 as an employee in any pharmaceutical company as part</p> <p>13 of their pharmacovigilance department?</p> <p>14 A Correct.</p> <p>15 Q You've never worked at a pharmaceutical</p> <p>16 company at all; right?</p> <p>17 A Correct.</p> <p>18 Q Have you ever been employed as an</p> <p>19 employee by any governmental health or regulatory</p> <p>20 authority?</p> <p>21 A Yes.</p> <p>22 Q Which one?</p> <p>23 A So when I was serving on the advisory</p> <p>24 committee, I was technically a FDA employee --</p> <p>25 federal employee.</p>	<p style="text-align: right;">Page 28</p> <p>1 BY MR. TOMASELLI:</p> <p>2 Q Dr. Kulldorff, I'm going to hand you what</p> <p>3 I've marked as Exhibit 1, which is your expert</p> <p>4 report in this matter; is that correct?</p> <p>5 A Yes.</p> <p>6 Q It's dated September the 9th, 2024;</p> <p>7 right?</p> <p>8 A I believe so. Yes.</p> <p>9 Q You have no other expert report in this</p> <p>10 litigation; is that right?</p> <p>11 SECRETARY: Did you --</p> <p>12 A Correct.</p> <p>13 SECRETARY: -- want to also -- a</p> <p>14 copy also?</p> <p>15 MR. BAUM: Hold on a second.</p> <p>16 COURT REPORTER: Watch your</p> <p>17 microphone.</p> <p>18 MR. BAUM: Off the record. Let's go</p> <p>19 off the record.</p> <p>20 THE VIDEOGRAPHER: The time is</p> <p>21 9:22 a.m., and we're off the record.</p> <p>22 (Whereupon, there was a recess taken</p> <p>23 from 9:22 a.m. to 9:24 a.m.)</p> <p>24 THE VIDEOGRAPHER: The time is</p> <p>25 9:24 a.m., and we are on the record.</p>
<p style="text-align: right;">Page 27</p> <p>1 Q When you were serving on the FDA's Drug</p> <p>2 Safety and Risk Management Advisory Committee, you</p> <p>3 were considered a FDA employee?</p> <p>4 A Yes.</p> <p>5 Q Okay. Any other?</p> <p>6 A So NIH is not a regulatory agency, but</p> <p>7 I've been employed by NIH. So I don't -- I don't</p> <p>8 think that qualifies to your criteria. But...</p> <p>9 Q Oh, fair enough.</p> <p>10 So in terms of a governmental health</p> <p>11 organization, you have been employed by the NI- --</p> <p>12 the NIH and the National Cancer Institute</p> <p>13 specifically?</p> <p>14 A Yes.</p> <p>15 Also, one year by the National In- --</p> <p>16 National Institute of Neuro- -- Neurologically [sic]</p> <p>17 and -- Disorders and Stroke -- NINDS</p> <p>18 Q Okay. The National Institute of Health's</p> <p>19 division regarding stroke and neurologic disorders?</p> <p>20 A Yes.</p> <p>21 Q Okay.</p> <p>22 (Whereupon, Exhibit MK 1, Expert</p> <p>23 report of Dr. Kulldorff, was marked</p> <p>24 for identification.)</p> <p>25</p>	<p style="text-align: right;">Page 29</p> <p>1 MR. TOMASELLI: Thank you.</p> <p>2 BY MR. TOMASELLI:</p> <p>3 Q After a very short break, Dr. Kulldorff,</p> <p>4 are you ready to proceed?</p> <p>5 A Yes.</p> <p>6 Q Great.</p> <p>7 We just marked as Exhibit 1 your expert</p> <p>8 report in this litigation; fair?</p> <p>9 A Yes.</p> <p>10 Q Looks like you brought a copy of it with</p> <p>11 you today; right?</p> <p>12 A Yes.</p> <p>13 Q Okay. You have no other expert report in</p> <p>14 this litigation; right?</p> <p>15 A Correct.</p> <p>16 Q Okay. Is there anything you need to</p> <p>17 correct or modify in your expert report that's</p> <p>18 Exhibit 1 as you sit here today?</p> <p>19 A There were a couple of grammar typos.</p> <p>20 But I don't think I have to correct them, so I think</p> <p>21 it's okay. I could stand by what's in there.</p> <p>22 Q Fair enough. We'll -- we'll excuse the</p> <p>23 grammar typos.</p> <p>24 But other than that, any substantive</p> <p>25 changes?</p>

8 (Pages 26 - 29)

<p style="text-align: right;">Page 30</p> <p>1 A No. 2 Q Fair enough. 3 All the opinions that you intend to offer 4 in this case are contained within that expert 5 report; right? 6 A Well, if you have other questions -- if 7 other questions are given to me, I'll ask -- I'll 8 answer whatever questions are given to me. 9 Q Right. 10 But as you sit here today, the ex- -- the 11 expert opinions that you intend to offer are 12 contained in the report? 13 A Well, if you ask me about other things, I 14 will try my best to answer anything you ask me. 15 Q Right. 16 But since you can't understand or 17 anticipate -- withdrawn. 18 Since you can't anticipate what I'm going 19 to ask you, in terms of what you were prepared to 20 testify about in this case, that's contained within 21 your report; right? 22 A Well, I would answer any questions that 23 anybody asks me, whether it's you or somebody else. 24 Q Fair enough. 25 Do you -- as you sit here today, do you</p>	<p style="text-align: right;">Page 32</p> <p>1 Q Well, that's why you couldn't find it. 2 On page three -- withdrawn. 3 Dr. Kulldorff, on page three of your 4 report, you state "In writing this report, I take 5 the same scientific approach that I've used for 6 decades in detection and evaluating potential 7 vaccine safety problems." 8 Do you see that? 9 A Yes. 10 Q And that's true? 11 A Yes. 12 Q Okay. Now, in reading your expert 13 report, it appears to me that you focused in on 14 three particular areas. 15 One of those, you analyzed Merck's 16 responses to the EMA's questions in connection with 17 the Article 20 procedure in 2015; is that right? 18 A Correct. 19 Q The second major topic was that you 20 evaluated the Chao study that was published in 2012; 21 is that right? 22 A Correct. 23 Q And the third major area is that you 24 evaluated Lucija Tomljenovic's disproportionate -- 25 -ality -- disproportionality analysis related to</p>
<p style="text-align: right;">Page 31</p> <p>1 have other opinions that you plan to offer at trial 2 in this case that are not in that report? 3 A Not me, personally. I don't know what 4 plans you have or my attorney has. 5 Q That's fine. 6 But in terms of you, personally -- 7 A I -- 8 Q -- as you sit here -- let me finish my 9 question. Sorry. Withdrawn. 10 As you -- for you, personally, and as you 11 sit here today, right now, you don't have any other 12 opinions that you plan to offer in this case, other 13 than the ones that are in your report? 14 A Correct. 15 Q Okay. Did -- other than any lawyers, did 16 anybody else help you write your report? 17 A No. I wrote it. 18 Q And on page two of your report, you 19 state, "In writing this report, I take the same 20 scientific approach that I've used for decades in 21 detection and evaluating potential vaccine safety 22 problems." 23 Right? 24 A On page two? 25 Oh, that's on page three.</p>	<p style="text-align: right;">Page 33</p> <p>1 POTS and primary ovarian insufficiency that was 2 generated in 2024; is that right? 3 A Correct. 4 Q And I apologize that I don't exactly know 5 how to say her name. 6 But if I say Ms. Tomljenovic; is that 7 okay? 8 A My ability to pronounce it correctly is 9 about the same level as yours. So don't ask me. 10 Q Okay. So I think we're on the same page; 11 fair? 12 A Correct. 13 Q Okay. And it's okay to call her analysis 14 a disproportionality analysis; right? 15 A Yes. 16 Q Now, we'll get into these a little bit 17 more. 18 But of all the issues that you addressed 19 in your expert report, they are related to data 20 pertaining to Gardasil that were published or became 21 available after January of 2011; correct? 22 A Some of it uses data before that year, I 23 think. 24 Q Some of the data that went into the 25 analyses were from prior to 2011.</p>

<p style="text-align: right;">Page 34</p> <p>1 A Yes.</p> <p>2 Q But the analysis that you analyzed and 3 that you talked about in your expert report -- the 4 Chao publication, the Article 20 procedure, and 5 Dr. Chung (phonetic) -- Tomljenovic's 6 disproportionality analysis -- those were published, 7 and -- and those analyses came after January of 8 2011; right?</p> <p>9 A Yes.</p> <p>10 The analysis were done after that date.</p> <p>11 Yeah.</p> <p>12 Q Okay.</p> <p>13 A Sorry for misunderstanding you.</p> <p>14 Q No. That's probably my -- my fault on 15 the question. I appreciate the clarification.</p> <p>16 Withdrawn.</p> <p>17 Obviously you saw Ms. Tomljenovic's 18 written expert report before you submitted your 19 expert report; is that right?</p> <p>20 A I saw parts of her expert report.</p> <p>21 Q And did you read all the entirety of her 22 expert report?</p> <p>23 Or did you just focus on the 24 disproportionality part?</p> <p>25 A I only saw part four of her report.</p>	<p style="text-align: right;">Page 36</p> <p>1 correct?</p> <p>2 MR. BAUM: Objection. Vague.</p> <p>3 A What -- what do you mean by "one 4 iteration"?</p> <p>5 BY MR. TOMASELLI:</p> <p>6 Q Well, my question is simply: Did -- did 7 that analysis change over time, based on the 8 parameters, based on the inputs, based on searching?</p> <p>9 And so my question to you is: Did you 10 see, essentially, one disproportionality analysis 11 from her?</p> <p>12 Or did you see an analysis that evolved 13 over time?</p> <p>14 A Well, she did many analysis by gender, by 15 age for different outcomes. And so -- and in the 16 part four of her report, there's a lot of different 17 analysis. And I only saw part of those analysis in 18 July.</p> <p>19 And then, when she ran more of those 20 different analysis, I saw additional ones in August.</p> <p>21 Q I understand. So let me see if I have 22 this right.</p> <p>23 In terms of your -- your review of 24 Ms. Tomljenovic's disproportionality analysis, you 25 saw part of the analysis in July which included</p>
<p style="text-align: right;">Page 35</p> <p>1 Q Okay. Do you know how far in advance you 2 received part four of Ms. Tomljenovic's report 3 before your expert report was due?</p> <p>4 MR. BAUM: Just objection. Vague.</p> <p>5 BY MR. TOMASELLI:</p> <p>6 Q Withdrawn.</p> <p>7 Dr. Kullendorff, your report is from 8 September of 2024; right?</p> <p>9 A Yes.</p> <p>10 Q And my question is: How far in advance 11 of September, 2024, did you look at the 12 disproportionality analysis?</p> <p>13 A So I saw some of the analysis in July. I 14 saw other parts of the analysis in August.</p> <p>15 Q Did the analysis change between July and 16 August?</p> <p>17 A None of the analysis that I saw in July 18 changed any substantial or anything I noticed for 19 later.</p> <p>20 But there were additional analysis done 21 that -- that I saw in August that I had not seen in 22 July.</p> <p>23 Q In terms of Ms. Tomljenovic's 24 disproportionality analysis related to POTS, you 25 saw, basically, one iteration of that analysis;</p>	<p style="text-align: right;">Page 37</p> <p>1 POTS; correct?</p> <p>2 A So some of the analysis in July was for 3 POTS. Yes.</p> <p>4 Q And you reviewed additional analyses in 5 August of this year; right?</p> <p>6 A Correct.</p> <p>7 Q My question is: In terms of, for 8 example, a POTS analysis that you saw in July, did 9 it change in August?</p> <p>10 A Not the -- the -- the analysis that I saw 11 in July did have any substantial change as for -- 12 (Whereupon, the court reporter 13 requests clarification.)</p> <p>14 A -- did not have any substantial changes 15 for what I saw in August.</p> <p>16 But I don't -- I don't remember exactly 17 which ones was one. But let's say I think she 18 focused on the females, maybe, in July, and maybe I 19 didn't see the male until August.</p> <p>20 But I don't remember exactly which ones I 21 saw in July versus August. But there were 22 additional analysis that she did for both the 23 females and males and different age groups and -- 24 and different time periods --</p> <p>25</p>

10 (Pages 34 - 37)

<p style="text-align: right;">Page 38</p> <p>1 Q Okay. 2 A -- and so on. 3 Q And so in terms of what you saw -- say it 4 was an analysis of females for POTS -- a 5 disproportionality analysis for females for POTS, 6 whatever you saw in -- in July, that analysis for 7 females did not change in August? 8 A Correct. 9 Unless there was an additional for a 10 different age group or for different time periods. 11 Because she did some of the time per- -- she did 12 different time periods. 13 Q Right. 14 A So some of those time periods I didn't 15 see in July. And then, if you did a different time 16 periods, the -- the ones I saw in July didn't 17 change. 18 But then, there was a different that was 19 for -- in August for a different time period. And 20 of course, the estimates are somewhat different. 21 Q Right. 22 Dr. Kulldorff, was, in your mind, 23 Dr. Tomljenovic's disproportionality analyses 24 prespecified? 25 MR. BAUM: Objection. Vague.</p>	<p style="text-align: right;">Page 40</p> <p>1 Q You don't have a specific recollection of 2 whether you talked to her or encountered any of her 3 literature prior to the summer of 2024? 4 A No. 5 I have never talked to her or 6 communicated with her in any manner before -- before 7 the summer of '24, that I know. 8 Q In terms of her research or publications 9 you're not aware, as you sit here today, whether you 10 were aware of those publications or her research 11 prior to the summer of 2024; is that right? 12 A So I might have encountered some of them. 13 But yeah, I don't remember all of the papers. 14 I mean, I read so many papers. I don't 15 remember exactly who -- who wrote what. 16 Q Totally understandable. 17 And I guess, I -- my only question is: 18 You don't have a specific recollection of reading 19 any of her papers or research prior to the summer of 20 2024? 21 A I might have recollection of the papers 22 without realizing that she -- her -- her name was on 23 it. 24 Q Okay. Again, you have not investigated 25 her credentials, so do you -- you don't know whether</p>
<p style="text-align: right;">Page 39</p> <p>1 A I think you have to ask her that 2 question. 3 BY MR. TOMASELLI: 4 Q Okay. You don't know, one way or the 5 other, whether the disproportionality analyses you 6 reviewed in July and August were all prespecified? 7 A You'd have to ask her that question. 8 I -- 9 Q You don't -- 10 A -- don't know. 11 Q -- know one way or the other? 12 A I don't know. 13 Q Do you understand, Dr. Kulldorff, that 14 Ms. Tomljenovic is not a physician? 15 A My guess is that she's not. But I -- I 16 mean, you'll have to ask her about her -- her own 17 credentials. 18 Q You did not investigate her credentials? 19 A No. 20 Q Had you ever heard of Ms. Tomljenovic or 21 encountered her in your professional work prior to 22 this interaction in 2024? 23 A I had never had any communication with 24 her prior to this. I may have seen some papers by 25 her, but I don't remember if I have or not.</p>	<p style="text-align: right;">Page 41</p> <p>1 she has any formal training in statistics or 2 advanced degrees in statistics or any of her bona 3 fides, so to speak? 4 A I don't think she has a Ph.D. in 5 statistics. 6 Q Do you know if she's ever had any formal 7 training in statistics? 8 A Most scientists have had, so I assume she 9 has. But I don't know the nature of it. 10 Q Did you talk with Ms. Tomljenovic about 11 her disproportionality analysis before it was 12 complete? 13 A Yes. 14 Q And did you meet in person? 15 A No. 16 Q Did you always talk to her over the phone 17 or Zoom? 18 A We -- I talked with her with Zoom -- on 19 Zoom. 20 Q And did you offer her any advice in terms 21 of her disproportionality analyses? 22 A Yes. 23 Q And what advice was that? 24 A To consider age as a potential 25 confounder.</p>

<p style="text-align: right;">Page 42</p> <p>1 Q What else?</p> <p>2 A I think that was it. At least, that was 3 the only major things.</p> <p>4 And she -- yeah.</p> <p>5 Q In terms of the advice that you remember 6 giving her in the summer of 2024, your 7 recollection's that you talked to her about 8 considering age as a potential confounder; is that 9 right?</p> <p>10 A Yes.</p> <p>11 Q And as you sit here today, you don't 12 recall any other specific advice that you gave her?</p> <p>13 A There was no other major advice. I might 14 have -- I don't remember if I did some other minor 15 things.</p> <p>16 Q And did you have e-mail communications 17 directly between you and her alone?</p> <p>18 A You mean, only the two of us?</p> <p>19 Q That's correct.</p> <p>20 A Only things that were also cc'd to the 21 attorneys.</p> <p>22 Q So your communications with 23 Ms. Tomljenovic always included a lawyer?</p> <p>24 A I think they were always cc'd on 25 everything.</p>	<p style="text-align: right;">Page 44</p> <p>1 last week during her deposition?</p> <p>2 A There was some discussions with my 3 attorney --</p> <p>4 MR. BAUM: Okay. So objection.</p> <p>5 You're starting to walk into 6 protected communications.</p> <p>7 BY MR. TOMASELLI:</p> <p>8 Q Have you learned anything about what 9 Ms. Tomljenovic said last week from anyone, other 10 than an attorney?</p> <p>11 A No.</p> <p>12 Q Do you know any other experts that are 13 consulting for the plaintiffs, besides 14 Ms. Tomljenovic?</p> <p>15 A You mean, if I know the names; if I know 16 them personally; or if I have communicated with 17 them?</p> <p>18 Q All of those.</p> <p>19 A So there is one. His name -- he's a 20 physician, I think, here in Boston. The -- the name 21 is escaping me now.</p> <p>22 Q Anybody else?</p> <p>23 A And then, there is Peter Gøtzsche, who -- 24 who I have met. He's a -- he's a very good 25 scientist.</p>
<p style="text-align: right;">Page 43</p> <p>1 Q Did she ever tell you why she performed 2 the disproportionality analysis in her expert 3 report?</p> <p>4 A I don't know if she specifically told me. 5 But it's obviously to determine whether there's a 6 relationship between Gardasil and these outcomes.</p> <p>7 Q A disproportionate analysis between 8 Gardasil and certain outcomes; correct?</p> <p>9 A Well, the ultimate goal is to know if 10 there is a relationship -- a causal relationship. 11 That's the goal of doing this analysis.</p> <p>12 Q Okay. Did Ms. Tomljenovic -- well, 13 withdrawn.</p> <p>14 Did you ever talk with Dr. Brinth about 15 Ms. Tomljenovic's disproportionality analysis?</p> <p>16 A No.</p> <p>17 Q Do you know that Ms. Tomljenovic sat for 18 a deposition, like you are doing today, that -- last 19 week?</p> <p>20 A Yes.</p> <p>21 Q And were you provided the transcript of 22 that deposition?</p> <p>23 A I don't think so, and I have not read it.</p> <p>24 Q Were you -- withdrawn.</p> <p>25 Do you know what she said on any topic</p>	<p style="text-align: right;">Page 45</p> <p>1 I don't think I know of the other ones.</p> <p>2 They might have been mentioned at some 3 point to me, or they might have popped up on a -- 4 on a -- on a -- on an e-mail that was sent out to 5 everybody, but I don't remember.</p> <p>6 Q Do you recall reviewing or analyzing any 7 expert report, other than Ms. Tomljenovic's?</p> <p>8 A I did not.</p> <p>9 Q Did you talk with Peter Gøtzsche about 10 his testimony or his report?</p> <p>11 A No.</p> <p>12 Q Do you know of any other biostatistician 13 that has worked with plaintiff's counsel with 14 respect to the Gardasil litigation?</p> <p>15 A No.</p> <p>16 Q You're the only biostatistician, that you 17 know of, that's been hired by the plaintiffs; is 18 that correct?</p> <p>19 A I don't know of -- of -- of others.</p> <p>20 So...</p> <p>21 Q And that's my --</p> <p>22 A If -- yeah.</p> <p>23 Q -- question.</p> <p>24 A If then -- if they -- yeah.</p> <p>25 (Whereupon, Exhibit MK 2,</p>

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<p style="text-align: right;">Page 46</p> <p>1 Materials-Considered List, was marked 2 for identification.)</p> <p>3 BY MR. TOMASELLI:</p> <p>4 Q I marked as Exhibit 2 what was provided 5 to us.</p> <p>6 And it's generally called a 7 materials-considered list. Do you see that, sir?</p> <p>8 A Yes.</p> <p>9 Q Did you prepare that?</p> <p>10 A No.</p> <p>11 Q Is there another materials-considered 12 list, other than that one, for you?</p> <p>13 A There was an earlier version of this, I 14 think.</p> <p>15 Q Is that -- is that the most complete 16 version that -- that you're aware of?</p> <p>17 A Actually, yeah. I -- I presume so. I 18 haven't seen this particular version before. So...</p> <p>19 Q Is -- and let me ask it this way.</p> <p>20 Does Exhibit 2 need to be supplemented or 21 updated in any way, as far as you're aware?</p> <p>22 A Since I haven't seen this before -- I 23 haven't read it carefully, I can't -- I don't if -- 24 I'm not aware of anything. But...</p> <p>25 Q As you sit here today, you're not aware</p>	<p style="text-align: right;">Page 48</p> <p>1 So that's what I relied on for the 2 report.</p> <p>3 Q Fair enough.</p> <p>4 And -- and for sure, that you relied on 5 your education and your experience and your 6 publications --</p> <p>7 A Yeah.</p> <p>8 Q -- and the things that are in your expert 9 report.</p> <p>10 What I'm trying to understand is if 11 there's additional materials that are not cited in 12 your expert report, are not on Exhibit 2 -- that 13 materials list -- that I should be aware of, 'cause 14 this is my chance to ask you about those?</p> <p>15 A Yeah. I don't think there's anything 16 else you need to be aware of.</p> <p>17 Q Okay.</p> <p>18 MR. BAUM: Joe, I noticed that 19 the -- the Klein depo transcript is not 20 on here. And I think he saw -- may have 21 seen that or portions of that.</p> <p>22 MR. TOMASELLI: Okay.</p> <p>23 MR. BAUM: And I'm not sure if the 24 Klen -- whether -- if the Klein depo had 25 been done at the time this was done.</p>
<p style="text-align: right;">Page 47</p> <p>1 of anything that is not contained on Exhibit 2 that 2 I should be aware of?</p> <p>3 A Well, I haven't even read it, so that 4 I -- obviously, I'm not aware of anything, since I 5 haven't read it.</p> <p>6 Q Well, take one minute or two to breeze 7 through it and see if -- see if I should be aware of 8 something else.</p> <p>9 A Okay. And for clarification, it's things 10 that have been sent to me about this case.</p> <p>11 Q Well, materials that you considered in 12 the case. Yes.</p> <p>13 Or did you cite all of those materials in 14 your expert report, generally?</p> <p>15 A Yeah. So if there's things that I cited 16 in my expert report that's not here, then, I 17 considered that, as well.</p> <p>18 Q Okay. But are you primarily relying on 19 the materials that you cited in your expert report 20 over the ones in Exhibit 2?</p> <p>21 A So what I relied on in my expert report 22 are the ones that was cited there.</p> <p>23 Q Uh-huh.</p> <p>24 A Plus my general knowledge a- -- about 25 epidemiology, biostatistics, vaccines, Gardasil.</p>	<p style="text-align: right;">Page 49</p> <p>1 MR. TOMASELLI: Fair enough.</p> <p>2 THE WITNESS: Yeah. I also think 3 the Chao deposition is probably missing 4 here.</p> <p>5 MR. TOMASELLI: You have Chao rough 6 on there. But...</p> <p>7 MR. BAUM: Yeah. That's at 12.</p> <p>8 BY MR. TOMASELLI:</p> <p>9 Q Withdrawn.</p> <p>10 Dr. Kulldorff, let me ask you just a 11 couple questions.</p> <p>12 A Yup.</p> <p>13 Q In connection with your work in this 14 case, you were provided a -- a few depositions of 15 Merck employees; is that right?</p> <p>16 A At least one.</p> <p>17 Q You did not cite any of their deposition 18 testimony in your expert report; is that correct?</p> <p>19 A That's correct.</p> <p>20 Q And you were provided -- that we just 21 talked about, you were provided the Chao and the 22 Klein (sp?) depositions from -- in connection with 23 your review of this case; right?</p> <p>24 A Correct.</p> <p>25 Q And you understand that those folks are</p>

13 (Pages 46 - 49)

<p style="text-align: right;">Page 50</p> <p>1 affiliated with Kaiser?</p> <p>2 A Yes.</p> <p>3 Q And you did not cite any of their</p> <p>4 deposition testimony in your expert report; correct?</p> <p>5 A Correct.</p> <p>6 Q Do you understand that the authors of</p> <p>7 Merck's Article 20 response have been deposed in</p> <p>8 this case?</p> <p>9 Did you know that?</p> <p>10 A Not -- not really.</p> <p>11 Q Your report, Exhibit 1, contains no</p> <p>12 opinions about a person named Jennifer Robi; is that</p> <p>13 right?</p> <p>14 A Correct.</p> <p>15 Q Do you know who she is?</p> <p>16 A I think she is a plaintiff.</p> <p>17 Q But you don't know anything else about</p> <p>18 her; right?</p> <p>19 A Pretty much not. No.</p> <p>20 I assume she took a Gardasil vaccine or</p> <p>21 something in her life. Otherwise, she wouldn't be a</p> <p>22 plaintiff.</p> <p>23 Q And --</p> <p>24 A But that's --</p> <p>25 Go ahead.</p>	<p style="text-align: right;">Page 52</p> <p>1 A No.</p> <p>2 Q Your report contains no opinions about</p> <p>3 Jennifer Robi; correct?</p> <p>4 A Correct.</p> <p>5 Q Your report contains no analysis or</p> <p>6 opinions regarding whether Gardasil or GARDASIL®9</p> <p>7 actually causes POTS; correct?</p> <p>8 MR. BAUM: Objection. Vague.</p> <p>9 MR. TOMASELLI: You can answer.</p> <p>10 A It doesn't contain -- con- -- contain any</p> <p>11 definite opinion of whether it does or does not.</p> <p>12 But it contains information that's highly relevant</p> <p>13 to that question.</p> <p>14 And that's necessary -- that is very</p> <p>15 important in making that determination.</p> <p>16 Q Let me ask it this way and see if we can</p> <p>17 agree.</p> <p>18 Withdrawn.</p> <p>19 Dr. Kulldorff, your expert report</p> <p>20 contains some information regarding Gardasil and</p> <p>21 POTS.</p> <p>22 For example, the Article 20 analysis in</p> <p>23 2015 dealt with POTS, as well as Ms. Tomljenovic's</p> <p>24 disproportionality analysis deals with POTS;</p> <p>25 correct?</p>
<p style="text-align: right;">Page 51</p> <p>1 Q Other than that?</p> <p>2 A No.</p> <p>3 Q Okay. Your report contains no analysis</p> <p>4 or opinions regarding whether Gardasil or GARDASIL®9</p> <p>5 actually causes POTS; correct?</p> <p>6 A I need to correct the previous statement.</p> <p>7 I think I also know that she probably</p> <p>8 lives in California.</p> <p>9 Q Okay. So --</p> <p>10 A Because this case is -- is litigated in</p> <p>11 California. So that's probably al- -- also what I</p> <p>12 know about her.</p> <p>13 Q All right. So let me --</p> <p>14 A So sorry for correct -- oh.</p> <p>15 Q No. No. Totally fine. I just don't</p> <p>16 want to talk over you.</p> <p>17 A Okay.</p> <p>18 Q Withdrawn.</p> <p>19 The things that you know about Jennifer</p> <p>20 Robi are that she probably took Gardasil at some</p> <p>21 point in her life and she lives in California;</p> <p>22 correct?</p> <p>23 A Correct. Yeah.</p> <p>24 Q Other than that, do you know anything</p> <p>25 about Jennifer Robi?</p>	<p style="text-align: right;">Page 53</p> <p>1 A Correct.</p> <p>2 Q Your report contains no analysis or</p> <p>3 opinion regarding the ultimate question of whether</p> <p>4 Gardasil or GARDASIL®9 actually causes POTS;</p> <p>5 correct?</p> <p>6 MR. BAUM: Objection. Vague and</p> <p>7 mischaracterizes what he just said.</p> <p>8 MR. TOMASELLI: You can answer.</p> <p>9 A It does not contain a definite conclusion</p> <p>10 of whether Gardasil causes POTS or POI or CRPS.</p> <p>11 I was not asked to provide such an</p> <p>12 opinion. I have not read the complete literature</p> <p>13 that's necessary to -- to provide such an opinion.</p> <p>14 So my report does not contain a definite</p> <p>15 conclusion on that question.</p> <p>16 Q And that's what I was asking,</p> <p>17 Dr. Kulldorff, is that I've read your expert report.</p> <p>18 And I was trying to confirm that your</p> <p>19 expert report contains no conclusion or opinion</p> <p>20 regarding whether Gardasil or GARDASIL®9 causes</p> <p>21 POTS; right?</p> <p>22 We agree on that?</p> <p>23 A So you're just repeating what I said,</p> <p>24 or --</p> <p>25 Q I'm trying to.</p>

<p>1 A Oh, yes.</p> <p>2 Q I'm trying to make sure we are on the 3 same page as one another.</p> <p>4 A Well, if what you just said repeated what 5 I said, then, that's correct.</p> <p>6 Q Okay. Your report contains no conclusion 7 regarding an opinion as to whether Gardasil causes 8 primary ovarian insufficiency; right?</p> <p>9 A So this answer's the same as for POTS.</p> <p>10 QOkay. Does your report contain a 11 conclusion as to your opinion as to whether Gardasil 12 causes POTS?</p> <p>13 A I have not offered any such opinion in 14 there -- or in my report.</p> <p>15 Q Do you offer such an opinion regarding 16 POI?</p> <p>17 A The report does not do that.</p> <p>18 Q Does your report offer a conclusion 19 regarding CRPS or chronic fatigue syndrome or 20 fibromyalgia?</p> <p>21 A The report does not offer such 22 conclusions.</p> <p>23 Q Does your report contain a analysis of 24 causes or risk factors that are -- that lead to the 25 development of POTS or primary ovarian insufficiency</p>	<p>Page 54</p> <p>1 to the Gardasil vaccine; correct? Mechanism?</p> <p>2 A I believe that's correct. The -- the 3 Merck report I think might have discussed the 4 mechanisms, but I don't go into that part of the 5 Merck report.</p> <p>6 Q And that's my -- and that's my question, 7 Dr. Kulldorff, is that -- that you in your expert 8 report provide no analysis or opinions regarding any 9 potential mechanism of harm with respect to 10 Gardasil; correct?</p> <p>11 A That is correct.</p> <p>12 Q Your report contains no analysis of 13 preclinical data or animal data or toxicology data 14 related to Gardasil; correct?</p> <p>15 A That is correct.</p> <p>16 Q Your report contains no opinions as to 17 the components or ingredients of Gardasil; correct?</p> <p>18 A That's correct.</p> <p>19 Q You are not an expert in the components 20 or ingredients of Gardasil; correct?</p> <p>21 A That's very much correct.</p> <p>22 Q Your report contains no opinions as to 23 whether Merck complied with U.S. law related to the 24 manufacture or distribution of Gardasil; correct?</p> <p>25 A That is correct.</p>
<p>1 or chronic fatigue syndrome or chronic regional pain 2 syndrome or fibromyalgia?</p> <p>3 A It contains information about potential 4 risk factors.</p> <p>5 Q Okay. Does your report attempt to detail 6 all the causes or risk factors for those conditions?</p> <p>7 A It does not.</p> <p>8 Q Does your report contain any analysis or 9 opinions regarding whether Gardasil or GARDASIL®9 is 10 an efficacious vaccine?</p> <p>11 A The report does not discuss efficacy at 12 all.</p> <p>13 Q Your report contains no systemic analyses 14 of GARDASIL®9 or Gardasil clinical trials; correct?</p> <p>15 A The report does not contain any 16 discussion of the clinical trials for Gardasil.BY 17 MR. TOMASELLI: Your report contains no analysis or 18 conclusion or opinion regarding the risk-benefit 19 profile of Gardasil or GARDASIL®9; correct?</p> <p>20 A That is correct.BY MR. TOMASELLI: Your 21 report contains no analysis of any antibody levels 22 related to the Gardasil vaccine; correct?</p> <p>23 A That is correct.</p> <p>24 Q Your report contains no analysis of 25 potential mechanisms of potential harm with respect</p>	<p>Page 55</p> <p>Page 57</p> <p>1 Q You are not a -- you are not an expert in 2 U.S. laws or regulations related to vaccines sold in 3 the United States; right?</p> <p>4 A I know a little bit about those things 5 but I'm not an attorney and I would say that you 6 have to be an attorney to be an expert on those 7 legal matters.</p> <p>8 Q Does your expert report contain any 9 opinions about Cervarix or any other HPV vaccine?</p> <p>10 A I don't think it does.</p> <p>11 Q Does your report contain an analysis of 12 anything the FDA, the CDC, the Health and Human 13 Services Center, does your opinion contain any 14 report regarding their analysis of whether Gardasil 15 causes POTS or POI?</p> <p>16 A Yes.</p> <p>17 Q It does? Where?</p> <p>18 A I think the Arana study, wasn't that by 19 CDC?</p> <p>20 Q It was.</p> <p>21 And what was the conclusion of the Arana 22 study, as best you are aware?</p> <p>23 A So the main thing of that study is what 24 they were looking at the specific -- they were 25 looking at the VAERS data and they were looking at</p>

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<p style="text-align: right;">Page 58</p> <p>1 the specific -- 2 (Whereupon, the court reporter 3 requests clarification.) 4 A The VAERS, V-A-E-R-S. 5 MR. TOMASELLI: All caps. 6 THE WITNESS: Vaccine -- 7 MR. TOMASELLI: V-A-E-R-S. 8 THE WITNESS: Vaccine Adverse Events 9 Reporting System. 10 BY MR. TOMASELLI: 11 Q Are you aware of any other data 12 pertaining to the FDA or CDC or Health and Human 13 Services review of whether Gardasil causes POTS? 14 A Yes. 15 Q Which one? 16 A There have been other papers by CDC 17 personnel. Like, for example, Shimabukuro have a 18 paper on the VAERS data. 19 Q With respect to Gardasil? 20 A Correct. 21 Q And what was the conclusion of the CDC 22 and FDA -- -A authors in that paper? 23 A Well, I would -- I will have to correct. 24 So -- so they -- no, I don't have to correct. 25 Sorry.</p>	<p style="text-align: right;">Page 60</p> <p>1 the field of vaccine safety monitoring for a couple 2 of decades; correct? 3 A Yes. 4 Q You've consulted and worked with 5 physicians, scientists, and statisticians both at 6 the FDA and the CDC; correct? 7 A Correct. 8 Q There are a variety of ways that vaccines 9 are monitored in the United States and around the 10 world; correct? 11 A Yes. 12 Q We'll talk more about these in -- in more 13 detail, but as a general matter, first of all, 14 manufacturers monitor safety through randomized 15 clinical trials, post marketing events that are 16 reported to them, as well as post marketing studies; 17 correct? 18 A Correct. 19 Q And the FDA and the CDC have a few 20 components of their monitoring systems as well; 21 right? 22 A Yes. 23 Q For example, one you just mentioned was 24 the VAERS spontaneous reporting system; correct? 25 A Correct.</p>
<p style="text-align: right;">Page 59</p> <p>1 Q Okay. 2 A You can remove that. 3 Q You can keep talking. 4 A So they did a data mining analysis of 5 Gardasil. 6 I have written myself papers together 7 with CDC and FDA employees on Gardasil, so I'm 8 obviously aware of those papers, articles. 9 Q Your report, Dr. Kulldorff, does not 10 discuss your own papers related to the safety of 11 Gardasil; correct? 12 A That is correct. 13 Q In your report -- and we'll talk about 14 this a little bit more -- but you talk about the 15 Chao 2012 publication; correct? 16 A I think it was 2012, yes -- yes. 17 Q Your expert report does not contain an 18 analysis of all the post marketing studies, whether 19 they be case reports, case series, cohort, 20 self-controlled case series, ecological data, your 21 report does not contain a complete analysis of the 22 post marketing data related to Gardasil and POTS or 23 POI; correct? 24 A Correct, yeah. 25 Q Now, my understanding is you've worked in</p>	<p style="text-align: right;">Page 61</p> <p>1 Q VAERS is Vaccine Adverse Event Reporting 2 System and is a all capped V-A-E-R-S; right? 3 A Yes. 4 Q And if we talk about VAERS, we are 5 talking the same language; right? 6 A I hope so. 7 Q And in terms of another way that the FDA 8 and CDC monitor vaccine safety is through the 9 Vaccine Safety Datalink? 10 A Correct. 11 Q And my understanding is that's a linked 12 population database with managed care institutions 13 where active and even realtime monitoring can take 14 place; right? 15 A Yes. 16 Q You, in fact, were involved in developing 17 and implementing statistical methods used by the VSD 18 project to evaluate vaccine safety; right? 19 A Yes. 20 Q In fact, I think you've said in the past 21 that the CDC's VSD system is the world's pre-eminent 22 vaccine safety surveillance system? 23 A I think so, yeah. 24 Q Do you believe that? 25 A Yes.</p>

<p>1 Q The FDA and CDC also use the Clinical 2 Immunization Safety Assessment Center, CISA, 3 C-I-S-A; right?</p> <p>4 A Yes.</p> <p>5 Q And that's an expert collaboration that 6 conducts individual clinical vaccine safety 7 assessments and research; right?</p> <p>8 A I believe so.</p> <p>9 Q And there's also another initiative by 10 the FDA called the Sentinel system?</p> <p>11 A Yes.</p> <p>12 Q And is that a population database system 13 similar to the -- the VSD?</p> <p>14 A It's similar. There are some 15 differences.</p> <p>16 Q Fair enough.</p> <p>17 And the PRISM, P-R-I-S-M, the 18 Post-Licensure Rapid Immunization Safety Monitoring, 19 is the vaccine component of the FDA Sentinel system; 20 right?</p> <p>21 A That's not per- -- completely correct, 22 no.</p> <p>23 Q How would you -- how would you describe 24 the PRISM in terms of the safe -- the Sentinel 25 system?</p>	Page 62	<p>1 epidemiologic studies; correct?</p> <p>2 A Correct.</p> <p>3 Q Those can be different types of 4 epidemiologic studies, such as case-controlled 5 studies or cohort studies or self-controlled case 6 series studies; right?</p> <p>7 A Yes. Others as well.</p> <p>8 Q And when you say other ways to do formal 9 epidemiologic studies, what -- what did you have in 10 mind there?</p> <p>11 A There are other self-controlled methods, 12 there are data mining methods.</p> <p>13 Q Okay. Would you agree that POTS and 14 POI -- and you understand when I say "POI" --</p> <p>15 A Yes.</p> <p>16 Q -- I'm talking about Primary Ovarian 17 Insufficiency?</p> <p>18 A Yeah.</p> <p>19 Q So withdrawn.</p> <p>20 Do you agree that POTS and POI were 21 diagnosed prior to the marketing of Gardasil?</p> <p>22 A I believe that's the case, but I'm not a 23 physician, I'm not an expert in these two things, so 24 it's better to ask other people about it.</p> <p>25 Q With all your work in the biostatistical</p>	Page 64
<p>1 A PRISM was a precursor to the Sentinel 2 system built on similar ideas as to the VSD but with 3 some important differences.</p> <p>4 And it was specifically set up, I think, 5 for one of the influenza vaccines. That then sort 6 of merged or developed into Sentinel.</p> <p>7 And I don't think PRISM as prog- -- as an 8 independent program exists anymore. So Sentinel 9 then expanded to also do drugs.</p> <p>10 Q So --</p> <p>11 A So sort of PRISM kind of ended and then 12 Sentinel became a bigger thing that doesn't -- 13 didn't -- it wasn't just one particular vaccine, but 14 it was multiple vaccines and most importantly, a -- 15 a large number of drugs also.</p> <p>16 Q Okay. If I understand correctly then, 17 the FDA Sentinel system absorbed the PRISM system -- 18 PRISM system and right now the Sentinel system is 19 used not only to monitor for vaccine safety but also 20 for pharmaceutical drug safety; correct?</p> <p>21 A So Sentinel right now is used for drugs. 22 I don't know if it's still used for -- for vaccines 23 or not.</p> <p>24 Q All right. There are also other ways to 25 monitor vaccine safety, such as through formal</p>	Page 63	<p>1 field and the vaccine safety with respect to 2 Gardasil, you know that POTS and POI were diagnosed 3 prior to Gardasil; right?</p> <p>4 A I believe it was, yes.</p> <p>5 Q And the same is true for chronic fatigue 6 syndrome, fibromyalgia, and other autoimmune 7 diseases; right?</p> <p>8 A Correct.</p> <p>9 Q POTS and POI occur and are diagnosed in 10 unvaccinated individuals; correct?</p> <p>11 A I believe so, yes.</p> <p>12 Q And the same, again, is true for chronic 13 fatigue syndrome, fibromyalgia, and other autoimmune 14 diseases; right?</p> <p>15 A So there are very few unvaccinated 16 individuals in -- in the world right now, but -- 17 so -- but it certainly I think could be diagnosed in 18 unvaccinated individuals.</p> <p>19 Q Well, when we talk about POTS or POI or 20 chronic fatigue syndrome, fibromyalgia, other 21 autoimmune diseases, those do occur in individuals 22 who are unvaccinated with Gardasil; right?</p> <p>23 A Yes, yeah.</p> <p>24 Q Adverse events of all types can happen in 25 groups that are unvaccinated as well as unvaccinated</p>	Page 65

<p style="text-align: right;">Page 66</p> <p>1 with Gardasil; right?</p> <p>2 A Correct, yeah.</p> <p>3 Q When large numbers of people are</p> <p>4 vaccinated, as with HPV vaccination, events in</p> <p>5 temporal proximity to vaccination are actually</p> <p>6 expected to occur; correct?</p> <p>7 A Yes.</p> <p>8 Q For example, I think I saw a paper that</p> <p>9 you wrote with respect to looking at the occurrence</p> <p>10 of optic neuritis after HPV vaccination; do you</p> <p>11 remember that?</p> <p>12 A I remember that paper, yes.</p> <p>13 Q And temporal associations with events</p> <p>14 such as optic neuritis will always occur.</p> <p>15 But that temporal association alone does</p> <p>16 not prove causality; correct?</p> <p>17 A Yes. Because there is somebody who is</p> <p>18 diagnosed with something after -- after a vaccine</p> <p>19 doesn't prove anything.</p> <p>20 But then, you have methods, for</p> <p>21 example -- self-control methods -- where you can</p> <p>22 evaluate that. And those methods can prove</p> <p>23 causality and has been used to prove causality</p> <p>24 in the -- in -- in other -- other situations.</p> <p>25 Q Sure. And let me separate those two</p>	<p style="text-align: right;">Page 68</p> <p>1 seizures "X" number of days after vaccines, cannot</p> <p>2 be used to prove causation.</p> <p>3 MR. TOMASELLI: I'm going to hand</p> <p>4 you what I've marked as Exhibit 4, which</p> <p>5 is a paper with the first author of S --</p> <p>6 MR. BAUM: What was Exhibit 3?</p> <p>7 MR. TOMASELLI: Oh. Withdrawn.</p> <p>8 Let's do this first then.</p> <p>9 (Whereupon, Exhibit MK 3, Rule 26</p> <p>10 Expert Disclosure for Martin</p> <p>11 Kulldorff, was marked for</p> <p>12 identification.)</p> <p>13 MR. TOMASELLI: Marking as Exhibit 3</p> <p>14 a Rule 26 expert disclosure for you,</p> <p>15 Dr. Martin Kulldorff.</p> <p>16 BY MR. TOMASELLI:</p> <p>17 Q And in this disclosure, there's an</p> <p>18 Exhibit A that has a curriculum vitae that has your</p> <p>19 name on it; right?</p> <p>20 A Yes, it does.</p> <p>21 Q And is this curriculum vitae for you</p> <p>22 reasonably accurate and up-to-date?</p> <p>23 A Well, it's dated a year ago, so I guess</p> <p>24 it's not completely up-to-date.</p> <p>25 Q Well, this is the one that was provided</p>
<p style="text-align: right;">Page 67</p> <p>1 for -- for a minute.</p> <p>2 So on the first point, you agree that</p> <p>3 temporal associations with events will always occur,</p> <p>4 but temporal association alone does not prove</p> <p>5 causality; right?</p> <p>6 A Well, it depends on what you mean with</p> <p>7 "temporal association."</p> <p>8 Because if -- if, for example, the</p> <p>9 measles vaccines, there is a temporal association,</p> <p>10 it's, like, in the sense that there's more febrile</p> <p>11 seizures after the measles vaccine --</p> <p>12 (Whereupon, the court reporter</p> <p>13 requests clarification.)</p> <p>14 THE WITNESS: Febrile seizures.</p> <p>15 MR. TOMASELLI: Febrile seizures --</p> <p>16 THE WITNESS: Okay.</p> <p>17 MR. TOMASELLI: -- I think is what</p> <p>18 you were saying.</p> <p>19 THE WITNESS: Sorry for my bad --</p> <p>20 MR. TOMASELLI: That's okay.</p> <p>21 A So there is a temporal association in the</p> <p>22 sense that there's more seizures seven to ten days</p> <p>23 after the vaccine than there are in other time</p> <p>24 intervals. And that can be used to prove causation.</p> <p>25 But the fact that there's one case of</p>	<p style="text-align: right;">Page 69</p> <p>1 to us.</p> <p>2 So do you have a curriculum vitae that is</p> <p>3 more up-to-date?</p> <p>4 A I do but I haven't provided that to my</p> <p>5 attorney.</p> <p>6 Q Why not?</p> <p>7 A I wasn't asked to provide it, I guess.</p> <p>8 This is the probably one that was most up-to-date in</p> <p>9 June when it was requested.</p> <p>10 Q All right. And are there significant</p> <p>11 updates that you would make to this curriculum vitae</p> <p>12 as you sit here today?</p> <p>13 A No, there are a few more publications.</p> <p>14 Q Fair enough.</p> <p>15 Other than a few more publications that</p> <p>16 have come out since the date of this curriculum</p> <p>17 vitae, otherwise it is reasonably up-to-date and</p> <p>18 accurate?</p> <p>19 A I think so.</p> <p>20 Q All right.</p> <p>21 A I think you should be happy with it.</p> <p>22 (Whereupon, Exhibit MK 4, Publication</p> <p>23 by Author Sridhar Published in 2017,</p> <p>24 was marked for identification.)</p> <p>25</p>

18 (Pages 66 - 69)

<p>1 BY MR. TOMASELLI:</p> <p>2 Q Exhibit 4 is a publication that is by</p> <p>3 first author of Sridhar, S-r-i-d-h-a-r, that was</p> <p>4 published in 2017; correct?</p> <p>5 A So -- oh, there it is.</p> <p>6 2017; correct, yes.</p> <p>7 Q And you are a coauthor of this paper;</p> <p>8 right?</p> <p>9 A Yes.</p> <p>10 Q Authored with folks with the U.S. FDA,</p> <p>11 Harvard, Johns Hopkins; correct?</p> <p>12 A FDA and Johns Hopkins. I was the only</p> <p>13 one I think from Harvard on this thing. So there's</p> <p>14 no coauthors from Harvard.</p> <p>15 Q All right. If you turn to page two,</p> <p>16 above figure one. So turn to page two.</p> <p>17 Above figure one on the left do you see a</p> <p>18 paragraph that says, "Although temporal</p> <p>19 associations."</p> <p>20 Do you see that?</p> <p>21 A Correct, yeah.</p> <p>22 Q You -- you write, "Although temporal</p> <p>23 associations of adverse events with vaccination will</p> <p>24 always occur, temporal associations alone do not</p> <p>25 prove causality"?</p>	<p>Page 70</p> <p>1 Q Okay.</p> <p>2 A And that's very -- that's very important</p> <p>3 because -- and that's why we have systems like the</p> <p>4 VSD and that we do proper studies.</p> <p>5 Q Okay. And in terms of adverse events</p> <p>6 such as POTS or POI or chronic fatigue syndrome,</p> <p>7 just because a single individual is vaccinated and</p> <p>8 then temporally is diagnosed with POTS or POI, that</p> <p>9 does -- that alone does not prove causality; true?</p> <p>10 A That one alone -- one person alone cannot</p> <p>11 prove causality.</p> <p>12 Q You then go on to say, in the same spot</p> <p>13 we were looking, "Because HPV vaccines are</p> <p>14 administered to young females who are more likely to</p> <p>15 develop autoimmune diseases irrespective of</p> <p>16 vaccination, these events could occur by chance</p> <p>17 alone."</p> <p>18 Do you see that?</p> <p>19 A Yes.</p> <p>20 Q And that's true?</p> <p>21 A Yes. And probably some will occur by</p> <p>22 chance alone.</p> <p>22 Q Young females, as you say here, are more</p> <p>24 likely to develop autoimmune disease irrespective of</p> <p>25 vaccination, just because of the time of life;</p>
<p>1 A Correct.</p> <p>2 Q Do you see that?</p> <p>3 A Yeah.</p> <p>4 MR. BAUM: Objection.</p> <p>5 BY MR. TOMASELLI:</p> <p>6 Q Do you stand by that?</p> <p>7 A Yes. And that means temporal association</p> <p>8 that a particular person has an event. Now, that's</p> <p>9 what that sentence means.</p> <p>10 Now, if you have a situation where you</p> <p>11 have information of -- from hundreds of people, for</p> <p>12 example, and you see that they all had a stroke or</p> <p>13 whatever, and there were two people in the first</p> <p>14 week after vaccination and then 90 people in the</p> <p>15 second week, and three week -- three people in the</p> <p>16 third week, and two people in the fourth week and so</p> <p>17 on, that is a form of temporal association of</p> <p>18 multiple people and that can be used to prove</p> <p>19 causation.</p> <p>20 Q Okay. In terms of a -- in terms of a</p> <p>21 single patient though, adverse events with</p> <p>22 vaccination will always occur and that temporal</p> <p>23 association just between that individual and the</p> <p>24 vaccination, that alone does not prove causality?</p> <p>25 A Correct.</p>	<p>Page 71</p> <p>1 right?</p> <p>2 A Yes. And most diseases have a different</p> <p>3 risk or age curve.</p> <p>4 Q Young females are more likely to develop</p> <p>5 POTS irrespective of vaccination, too; correct?</p> <p>6 A I don't know what the age curve is for</p> <p>7 POTS, but there is sort of an age curve.</p> <p>8 Q But you would expect too that young</p> <p>9 females do develop POTS irrespective of vaccination;</p> <p>10 right?</p> <p>11 A Some could do that.</p> <p>12 Q And the same is true with respect to POI.</p> <p>13 In fact, POI is a condition of young</p> <p>14 females, irrespective of vaccination?</p> <p>15 A That can happen also irrespective of</p> <p>16 vaccination.</p> <p>17 Q Autoimmune diseases, POTS, primary</p> <p>18 ovarian insufficiency, can occur by chance alone;</p> <p>19 correct?</p> <p>20 A It can occur irrespectively of vaccine,</p> <p>21 so it's by chance alone in terms of the vaccine.</p> <p>22 But there could be some other reason</p> <p>23 that's triggering it that's not due to chance but</p> <p>24 some other exposure.</p> <p>25 Q Fair enough.</p>

<p>1 But in terms of --</p> <p>2 A So usually there's some reason for it, 3 it's not just out of the blue. There's usually some 4 reason of one type or the other.</p> <p>5 Q In terms of -- in terms of vaccination in 6 an adverse event, the fact that an adverse event 7 occurs temporally after vaccination can happen by 8 chance alone?</p> <p>9 A That can happen by chance alone.</p> <p>10 Q Now, outside of being hired in this case, 11 I think you've mentioned previously you've analyzed 12 data and published medical articles on the safety of 13 Gardasil specifically; right?</p> <p>14 A Correct.</p> <p>15 Q You've published these articles with 16 colleagues from FDA, CDC, Harvard, Vanderbilt, Johns 17 Hopkins, and other academic institutions; right?</p> <p>18 A All those for sure. Vanderbilt probably 19 for sure.</p> <p>20 I don't remember exactly all the 21 locations, so -- but that's probably true since you 22 looked up.</p> <p>23 Q You -- when you've published papers in 24 your analyses, you were focused on public safety and 25 providing an accurate view of the data related to</p>	<p>Page 74</p> <p>1 My question was supposed to be Gardasil 2 specific --</p> <p>3 A Okay.</p> <p>4 Q -- so withdrawn.</p> <p>5 In -- in connection as you sit here 6 today, with respect to Gardasil specifically, when 7 you authored papers did you find that your coauthors 8 were also interested in providing an accurate view 9 of the data related to the safety of Gardasil?</p> <p>10 A So those coauthors that I interacted with 11 directly, yes. There will -- might also be 12 coauthors that I didn't really interact with that 13 closely and therefore I can't really judge them on 14 the matter.</p> <p>15 Q As you sit here today, you are not aware 16 of a coauthor that -- that you published with that 17 was not concerned about the safety of Gardasil at 18 all; right?</p> <p>19 A For Gardasil, I have -- I have to look 20 up -- of those I know who were on the papers, that's 21 correct.</p> <p>22 Q Okay.</p> <p>23 A I would have to look up the authors to 24 see if any of those who are -- who are maybe not so 25 much hundred percent, if they are on those papers or</p>
<p>1 the safety of Gardasil; right?</p> <p>2 A Correct.</p> <p>3 Q When you coauthored those papers, did you 4 find that your coauthors were also interested in and 5 focused on patient safety?</p> <p>6 A That's the whole purpose of doing the 7 studies.</p> <p>8 Q So yes?</p> <p>9 A Yes.</p> <p>10 Q When you authored those papers, did you 11 find that your coauthors were interested in 12 providing an accurate view of the data related to 13 the safety of Gardasil?</p> <p>14 A So most of my colleagues for sure, one 15 hundred percent. There are some colleagues I would 16 not maybe say that for.</p> <p>17 Q With respect --</p> <p>18 A But --</p> <p>19 Q -- to --</p> <p>20 A But the question is then is that respect 21 to Gardasil.</p> <p>22 So I would have to look up exactly who my 23 coauthors are on the Gardasil papers to see if -- if 24 that question is about any of them.</p> <p>25 Q Fair enough, Dr. Kulldorff.</p>	<p>Page 75</p> <p>1 not. 2 (Whereupon, Exhibit MK 5, Paper 3 Authored by Gee Published in 2011, 4 was marked for identification.)</p> <p>5 BY MR. TOMASELLI:</p> <p>6 Q I'm marking as Exhibit 5 a paper with a 7 first author of Gee, Julian Gee, G-e-e, that was 8 published in 2011; do you see that?</p> <p>9 A Yes.</p> <p>10 Q And you are a coauthor of this paper; 11 right?</p> <p>12 A Correct.</p> <p>13 Q These coauthors, like you, cared about 14 getting the analysis correct; right?</p> <p>15 A For this particular paper or in general?</p> <p>16 Q Yes, for this particular paper?</p> <p>17 A What I know, I have no -- I have no 18 knowledge to the opposite.</p> <p>19 Q Do you remember this study?</p> <p>20 A Yes.</p> <p>21 Q How did this study come about, sir?</p> <p>22 Like, what -- what was the reason for this study?</p> <p>23 A So just hold on a second.</p> <p>24 So in the Vaccine Safety Datalink, we 25 pioneered what's called rapid cycle analysis where</p>

20 (Pages 74 - 77)

<p>1 we used sequential statistical methods. So using 2 VSD data for -- on a weekly basis. 3 So when there is a new vaccine, we would 4 get weekly reports of who got the vaccines and were 5 there any adverse reactions -- or adverse events 6 of -- on the particular list of concern. 7 So we set up this system and that's 8 what's then used every time there was a new vaccine 9 coming out on the market. 10 So we had done this for previous vaccines 11 and -- and then when Gardasil came on the market as 12 a new product, we evaluated that with the rapid 13 cycle analysis with weekly analysis. 14 And the point is that if there's a 15 problem, we wanted to detect that as soon as 16 possible. So we don't want to wait a year or two or 17 so on. We want to, sort of, look at it 18 completely -- very completely. 19 But then you had to have special 20 statistical methods to take into account the fact 21 that you were looking at it repeatedly so you won't 22 get too many false positives. 23 So we developed that system and I was an 24 integral part in that development of the system. 25 And then that was used for when the new vaccine came</p>	<p>Page 78</p> <p>1 A Correct, yes. 2 Q That was correct at the time in 2011 when 3 published; right? 4 A Correct. 5 Q Do you recall saying a similar statement 6 in 2016 in a paper with Dr. Yih? 7 A I don't recall it, but I might have -- 8 might very well have. 9 Q There's a person that you worked with and 10 mentored named Katherine Yih, Y-i-h? 11 A Yes. 12 Q Is that how you say that? 13 A Yih. 14 Q Yih. So like Y-e-e but Y-i-h? 15 A Y-i-h, Yih. 16 Q Okay. I just want to make sure I say it 17 right, that's all. 18 A Okay. 19 Q Or as best I can. 20 (Whereupon, Exhibit MK 6, Paper 21 Published by Katherine Yih in 2016, 22 was marked for identification.) 23 BY MR. TOMASELLI: 24 Q I'm going to hand you what I've marked as 25 Exhibit 6, which is a paper by -- with a first</p>
<p>1 on the market. 2 Q And when you say that part of what you 3 did was to get data every week on -- on a vaccine 4 and you said "we," who is we? 5 A So I was part of the Vaccine Safety 6 Datalink at the time with coauthors who were also 7 part of the Vaccine Safety Datalink. Not everybody 8 in VSD, but many people, so -- 9 Q Would that include people at the FDA and 10 at CDC? 11 A At CDC, yes. 12 Q And so -- 13 A For example, Eric Weintraub here. 14 Q And so in terms of people at CDC, they 15 are getting weekly information regarding the safety 16 of Gardasil and other vaccines? 17 A Yeah. So when there's a new vaccine, 18 like Gardasil, usually we monitor for maybe a couple 19 of years with weekly analysis. 20 Q In your publication here on the first 21 page, on the right-hand column about five lines 22 down, do you see that it says, "Pre-licensure 23 clinical trials have shown no evidence for any major 24 safety problems." 25 Do you see that?</p>	<p>Page 79</p> <p>1 author of Dr. Yih, Y-i-h, and it was published in 2 2016; is that right? 3 A It was published in 2016 and it was made 4 available online 2015. 5 Q And if you turn to -- well, withdrawn. 6 This was an evaluation that you were 7 involved in; right? You were coauthor? 8 A Yes. 9 Q And it was an evaluation of venous 10 thromboembolism after Gardasil vaccination; correct? 11 A Correct. 12 Q If you turn over to page two, top left, 13 about four lines down, do you see that it says, "No 14 safety issues were identified in pre-licensure 15 studies involving approximately 21,000 subjects age 16 nine to 26 years." 17 Do you see that? 18 A Correct. 19 Q And that was correct as of 2016; right? 20 A Yes. 21 Q And you go on to say in the next 22 paragraph, "Post licensure surveillance identified a 23 possible increased risk of venous thromboembolism 24 after Gardasil vaccination in the first 2.5 years of 25 passive surveillance in the VAERS database. VTE" --</p>

21 (Pages 78 - 81)

<p style="text-align: right;">Page 82</p> <p>1 or that's venous thromboembolism -- "was reported 2 more frequently following Gardasil than expected 3 using other vaccines for comparison."</p> <p>4 Do you see that?</p> <p>5 A Yes.</p> <p>6 Q And the cite, number three, for that is a 7 publication by Slade in 2009; is that right?</p> <p>8 A Yes.</p> <p>9 Q And Slade, as you know, is a 10 disproportionality analysis performed by FDA and CDC 11 related to the early data from VAERS pertaining to 12 Gardasil; right?</p> <p>13 A Yeah, so I don't actually remember that 14 paper very well. I have not read that recently.</p> <p>15 Q Fair enough.</p> <p>16 A So I don't want to, sort of, say anything 17 about what it contained or not.</p> <p>18 Q That's fine. We'll -- we'll take a look 19 at it.</p> <p>20 You say in section 2.2 at the bottom 21 left, "A self-controlled risk interval design was 22 used. This design uses only vaccinated cases 23 occurring in a pre-specified risk or comparison 24 interval and it controls for all potential time in 25 variant confounders," and then you go on to -- to</p>	<p style="text-align: right;">Page 84</p> <p>1 data day one through 27 and 30 on day eight to 28. 2 Well, that's what you would expect by chance. So 3 then you'd say, Well, from this analysis then 4 there's no evidence of an excess risk.</p> <p>5 There could still be because maybe the 6 risk is all those 28 days and then subsequent risk, 7 much less. But from this analysis, there's no 8 evidence of that.</p> <p>9 On the other hand, if you find 30 cases 10 in day one to seven and only ten on day eight to 28, 11 you will start thinking, Hmm, that's strange because 12 if another poss- -- if it doesn't have anything do 13 with the vaccine, you would expect it to be sort of 14 evenly distributed and it's not.</p> <p>15 And -- so then you would say, Okay, this 16 is maybe evidence to say that something is going on 17 with this vaccine. Now --</p> <p>18 (Whereupon, the court reporter 19 requests clarification.)</p> <p>20 A -- some evidence that something goes only 21 with these vaccines.</p> <p>22 Now they -- so what is an advantage of 23 the self-controlled method is that it adjusts for 24 any between person confounding.</p> <p>25 So when you compare people that are</p>
<p style="text-align: right;">Page 83</p> <p>1 list a few of those.</p> <p>2 Do you see that?</p> <p>3 A Yeah.</p> <p>4 Q What is a self-controlled case series or 5 risk interval analysis? How does that work?</p> <p>6 A So a self-controlled risk interval.</p> <p>7 So you have people who got the vaccine on 8 day zero -- we define it as day zero. And then you 9 might look for days post that, so let's say you can 10 look for day one to 28.</p> <p>11 And then you can see are there -- how 12 many seizures, for example, occur in day one to 13 seven versus how many seizures occur day eight to 14 28.</p> <p>15 If the null hypothesis is true that 16 there's no relationship between the vaccine and 17 seizures, you will expect to have about the same 18 number of seizures in each of those 28 days, which 19 means you will expect to have about three times as 20 many in the control window eight to 28 versus the 21 risk window one to seven.</p> <p>22 So you can then look to see, well, how 23 many cases were there in one to seven and how many 24 were there two to 28.</p> <p>25 So let's say there were ten cases in this</p>	<p style="text-align: right;">Page 85</p> <p>1 vaccinated to unvaccinated, they can be confounding 2 because they might be different for some reasons. 3 But this is self-controlled because you can't 4 compare the same person to the same person.</p> <p>5 So there can still be various biases, as 6 in all observational studies, but they are of a 7 different nature than, for example, a cohort study 8 or case-control study.</p> <p>9 BY MR. TOMASELLI:</p> <p>10 Q Okay.</p> <p>11 A So they have different -- so self-control 12 method has certain strengths that these others don't 13 have, but they can also be potentially biases.</p> <p>14 One is, for example, maybe you find that 15 there is more seizures but it's not due to the 16 vaccine you are studying; they had -- took another 17 vaccine on the same day and it's this other vaccine 18 that is causing the seizures.</p> <p>19 Q I understand.</p> <p>20 A So it could be confounding or other 21 types.</p> <p>22 Q So stated simply maybe, different 23 epidemiologic designs have different benefits and 24 different limitations; fair?</p> <p>25 A Correct.</p>

22 (Pages 82 - 85)

<p style="text-align: right;">Page 86</p> <p>1 Q Okay. 2 A Very much so. 3 Q If you go to page 175 of your paper -- 4 and tell me when you are there? 5 A Yes. 6 Q The -- in the middle of the page, right 7 column, there's a paragraph that starts, "None of 8 the three co-primary analyses." 9 Do you see that? It's about five lines 10 down. 11 A Okay. 12 Q On the right. 13 Do you see that? 14 A Yeah. 15 Q All right. It says -- your paper says -- 16 withdrawn. 17 Your paper says, "None of the three 18 co-primary analysis demonstrated any association 19 between Gardasil and venus thromboembolism 20 regardless of dose number or risk interval table 21 three." 22 Do you see that? 23 A Correct. 24 Q And if we look at table three, we turn 25 over one page, table three is at the bottom of the</p>	<p style="text-align: right;">Page 88</p> <p>1 confidence interval that includes the number one, 2 which this one does, 1.0, that -- that you refer to 3 that as not statistically significant? 4 A That's tradition. 5 Q Okay. 6 A For better or worse. 7 Q And -- and then if -- if the interval 8 does not include one, the tradition is to say that 9 it is statistically significant; right? 10 A That's the tradition, yeah. 11 Q If -- if the data here is not 12 statistically significant, would you agree that 13 statistically no association was demonstrated? 14 A There was no statistical significant 15 relationship. 16 Q Right. 17 A That's slightly different than what you 18 said. 19 Q Okay. So if it's not statistically 20 significant, there's no significant association 21 demonstrated; right? 22 A No, that's not the same thing. 23 Q What did you say? 24 A There was no statistically significant 25 relationship.</p>
<p style="text-align: right;">Page 87</p> <p>1 next page; right? 2 A Yes. 3 Q And if we just take the first analysis, 4 so "Analysis with all definite VTE cases with no 5 adjustment for contraceptive use," and we just look 6 at the first row after that, which is, "Dose one 7 with days in risk interval one to 28." 8 Do you see that row, sir? 9 A Yes. 10 Q And the relative risk is calculated to be 11 0.60 -- 0.60 with a 95 percent confidence interval 12 of 0.15 to 2.27? 13 A Correct. 14 Q Is that right? 15 A Yeah. 16 Q And does that mean that -- that point 60, 17 does that mean there's a 40 percent reduction of 18 risk on Gardasil? 19 A Not necessarily because we have a 20 confidence interval between 0.15 and 2.27. 21 Q Okay. 22 A So the -- we have 95 percent confidence 23 that it's somewhere between 0.15 and 2.27. 24 Q And is it pretty typical for researchers 25 such as yourself when there's a 95 percent</p>	<p style="text-align: right;">Page 89</p> <p>1 Q If it's not statistically significant, 2 would you agree that there's no evidence of a 3 decreased risk or increased risk? 4 MR. BAUM: Objection. Vague. 5 BY MR. TOMASELLI: 6 Q You can answer. 7 A There's no statistically significant 8 evidence for it. 9 Q There's no statistical -- withdrawn. 10 When the -- when this result, this point 11 six that has a confidence interval that spans one, 12 if that's not statistically significant, there's no 13 evidence of a decreased risk or an increased risk; 14 is that right? 15 MR. BAUM: Objection. 16 A No, that's not the same thing. 17 BY MR. TOMASELLI: 18 Q Okay. What would you say? 19 A So I -- I'm sorry for being difficult 20 here. 21 Q You are not being difficult. 22 I just want to know when a lower bound 23 and an upper bound span one in the 95 percent 24 confidence interval, does that provide evidence of 25 risk or not?</p>

23 (Pages 86 - 89)

<p style="text-align: right;">Page 90</p> <p>1 A So I have to distinguish between 2 statistical significance and clinical significance. 3 So for example, you could have a result 4 that is statistically significant but it's not 5 clinically significant. 6 Q Okay. 7 A If -- 8 Q And let's -- and if it helps, let me -- 9 let me try a different question. 10 A Okay. 11 Q I want to separate those two. 12 So I think what you said is that it is 13 possible to have a statistically significant result 14 that is not clinically meaningful; right? 15 A Correct. 16 Q In terms of a statistics and not -- 17 setting the clinical question to the side, so in 18 terms of statistics. 19 When your confidence interval spans one 20 and it's not statistically significant, there's not 21 evidence for an increased risk; right? 22 MR. BAUM: Objection. Vague. 23 A Well, there is no statistically 24 significant evidence for increased risk. 25</p>	<p style="text-align: right;">Page 92</p> <p>1 A Uh-huh. 2 Q Is that a yes? 3 A Yes. 4 Q Okay. And the reason we have 5 statisticians, of course, is to try to determine or 6 help us determine whether that five and three are 7 actually different. 8 We know they are different in numbers but 9 are they actually different in terms of risks in the 10 population; right? 11 A Yeah. So we want to determine whether 12 that could potentially be as to chance or not. 13 Because there will always be some -- if 14 you compare two groups, it will rarely be the same 15 exact numbers, so there will typically be a little 16 bit more, one than others, which happened by chance. 17 If you flip a coin ten times, you will 18 most often not get five and five; you will get four, 19 six, or three or seven, just by the chance. 20 So the purpose of statistics is to 21 determine if what we see, could that be plausibly 22 due to just chance because if it's not plausible due 23 to chance, then that's evidence that there's 24 something else that's causing it and not chance. 25 That could be causal or it could be confounding.</p>
<p style="text-align: right;">Page 91</p> <p>1 BY MR. TOMASELLI: 2 Q The reason that we have -- well, 3 withdrawn. 4 In terms of a risk ratio or relative 5 risk, just as an example, that is 1.82, with a 6 95 percent confidence interval from .68 to 4.89, 7 that's a not statistically significant result; 8 correct? 9 And it's not -- it's not in this paper. 10 A Okay. That's not statistically 11 significant for a risk ratio. 12 Q And in terms of a risk ratio that is not 13 statistically significant, you would agree that that 14 is not evidence of a statistically significant 15 relationship; correct? 16 A Correct. 17 Q The reason that we have -- and we pay 18 them well, I'm sure -- statisticians like yourself, 19 is because when we compare two groups of people and 20 you say -- say, there's a hundred in each group and 21 we are looking at events that occur -- there may be 22 five events in one group and three events in 23 another -- we can agree that five and three are 24 different in terms of numerical, right, they're -- 25 they're -- they're different in numbers; right?</p>	<p style="text-align: right;">Page 93</p> <p>1 Q If the confidence interval -- the 2 95 percent confidence interval includes one, any -- 3 any difference in the numbers themselves could be 4 simply due to chance? 5 A And that is correct, yeah. 6 Q Okay. 7 MR. TOMASELLI: It takes dexterity. 8 (Whereupon, Exhibit MK 7, Publication 9 by Katherine Yih Published in 2018, 10 was marked for identification.) 11 MR. TOMASELLI: Withdrawn. 12 BY MR. TOMASELLI: 13 Q I'm handing you is what I've marked as 14 Exhibit Number 7, which is a publication by Dr. Yih 15 from 2018; is that right? 16 A Yeah, it was published in 2018. 17 Q And you are a coauthor of this paper; is 18 that correct? 19 A Correct. 20 Q You authored this paper with coauthors 21 from Harvard; correct? 22 A From Harvard and from FDA and, I believe, 23 also -- yeah, Harvard and FDA. 24 Q And are the coauthors on this paper with 25 you, are they competent?</p>

24 (Pages 90 - 93)

<p style="text-align: right;">Page 94</p> <p>1 A They are competent in their respective 2 areas. 3 Q But -- 4 A But they are not all competent in, for 5 example, epidemiology or in, for example, 6 biostatistics, etc. 7 Q Everybody -- everybody is a team player 8 on this publication and -- 9 A That is true. 10 Q -- just like you are not an expert on all 11 things physician- or clinical-related when you 12 publish with clinicians; right? 13 A Correct. Yeah. 14 Q All right. Like you, all of these 15 people, as best you know, they care about public 16 health and safety; right? 17 A I hope so. 18 Q They care about getting the analysis 19 correct? 20 A I hope so. 21 Q This paper used a methodology called a 22 temporal -- or tree-temporal scans statistic; right? 23 A Yes. 24 Q The way I under- -- well, withdrawn. 25 You actually developed that methodology</p>	<p style="text-align: right;">Page 96</p> <p>1 of nine year olds; is that right? 2 A I don't remember. 3 Q You can take a look at the abstract and 4 confirm it, if you'd like. 5 A So that is correct. 6 Q Now, you talked a little bit earlier 7 about the advantages or how a self-controlled 8 analysis works; right? 9 A Correct. 10 Q Would -- is -- is that -- do those also 11 apply to this paper? 12 A Correct. 13 Q Would you agree that your TreeScan method 14 has a very high power to detect -- to detect rare 15 events? 16 A Not necessarily, no. 17 Q Do you consider your TreeScan method to 18 be a -- a method of signal detection? 19 A Yes. 20 Q Would you agree that not all signals 21 represent true excess risk? 22 A That is correct. 23 Q If a signal is detected in any analysis, 24 you would suggest that that be followed up with more 25 formal epidemiological investigations, true?</p>
<p style="text-align: right;">Page 95</p> <p>1 as a way of studying vaccine safety; right? 2 A I developed the methodology, not 3 specifically for vaccine safety, but for vaccine and 4 drug safety, occupational safety, etc. 5 Q When we talk about the TreeScan, you have 6 to think of it actually as an upside down tree; is 7 that right? 8 A Sort of, yeah. 9 Q They're general health groupings that 10 then go into even smaller health groupings that go 11 into more specific diagnoses; right? 12 A Yes, you read it correctly. 13 Q And in this paper, for example, you were 14 able to look at over 7,000 outcome categories and 15 over 600 time intervals and -- so -- so with more 16 than 4.8 million potential clusters to evaluate; 17 right? 18 A That sounds right. I haven't checked the 19 exact number, but that sounds right. 20 Q Tree scanning is a method, again, that 21 you helped develop that can analyze thousands of 22 potential outcomes in multiple different time 23 windows; right? 24 A That is correct. 25 Q You, in this analysis, had a lower bound</p>	<p style="text-align: right;">Page 97</p> <p>1 A Other epidemiological investigations, 2 that's true. 3 Q Did you say "other" -- 4 A Other. 5 Q -- epidemiologic investigations? 6 A Correct, yes. 7 Q Okay. 8 A I think this is a formal investigation. 9 So I'm sorry for just picking the words. 10 Q Let's take a look at the first page of 11 this paper, if we can? 12 A Okay. 13 Q In the -- where -- where you start in the 14 introduction. 15 Do you see where you say, "Despite the 16 cancer-preventing promise of HPV vaccines and 17 national recommendations for routine HPV vaccination 18 of females and males at age 11 and 12 years, HPV 19 vaccine coverage in the United States lags behind 20 that of other adolescent vaccines more than a decade 21 after the first HPV vaccine was licensed." 22 Do you see that? 23 A Yes. 24 Q You go on to say, "One reason for this 25 persistent concern" -- sorry, withdrawn.</p>

25 (Pages 94 - 97)

<p style="text-align: right;">Page 98</p> <p>1 You go on to say, "One reason for this is 2 persistent concern about the safety of HPV vaccines 3 on the part of parents and the public." 4 Do you see that? 5 A Yes. 6 Q And then you go on to say, "The 7 scientific literature generally does not bear out 8 these worries." 9 Do you see that? 10 A Yes. 11 Q And that was true as of this time; 12 correct? 13 A I don't know if that was true, actually. 14 Q Well, you're a coauthor; right? 15 A Yeah. 16 Q You go on to say after that sentence, "A 17 substantial body of published evidence has 18 accumulated regarding the safety of quadrivalent 19 Gardasil, Merck and Co., White House Station, New 20 Jersey..." And then, you cite five through 15. 21 And then, you say, "...which constituted 22 93 percent of all HPV vaccine doses distributed in 23 the United States through September of 2015," with 24 a -- with a cite number 16. And you say, "...with 25 no confirmed safety problems identified to date,</p>	<p style="text-align: right;">Page 100</p> <p>1 201 paper; correct? 2 A Correct. 3 Q Number eight is the Grimaldi-Bensouda 4 publication from 2014; correct? 5 A Correct. 6 Q Number nine -- footnote nine is 7 Langer-Gould from 2014; correct? 8 A Correct. 9 Q Number 10 is Scheller from 2015; correct? 10 A Correct. 11 Q Number 11 is Naleway from 2016; correct? 12 A Correct. 13 Q Number 12 is the Yih, Y-i-h, paper that 14 we just looked at from 2016; right? 15 A Correct. 16 Q Number 13 is Grimaldi-Bensouda from 2017; 17 correct? 18 A Correct. 19 Q Number 14 is Feiring, F-e-i-r-i-n-g, from 20 2017; correct? 21 A Correct. 22 Q And number 15 is the Miranda study from 23 2017; right? 24 A Correct. 25 Q And those are the papers that you all</p>
<p style="text-align: right;">Page 99</p> <p>1 other than syncope and skin infections," and you 2 cite number five. 3 Do you see that, sir? 4 A Yes. 5 Q All right. Now, you have citations in 6 your publication for a variety of these 7 propositions; right? 8 A Correct. 9 Q So, for example, when you say there's a 10 substantial body of published evidence, you actually 11 cite ten or 11 publications there; correct? 12 A I think. Yes. 13 Q The first one that you cite is footnote 14 five, the Klein paper; correct? 15 A Correct. 16 Q Number six is the Chao paper; correct? 17 A Correct. 18 Q Let me just -- sorry, you'll -- you just 19 have to wait until I finish my question; okay? 20 Sorry about that. 21 Withdrawn. 22 The footnote six is the Chao paper; 23 correct? 24 A Correct. 25 Q Footnote seven is the Arnheim Dahlström</p>	<p style="text-align: right;">Page 101</p> <p>1 cited when you said that the scientific literature 2 does not bear out concern for safety of HPV 3 vaccines; correct? 4 A They were cited for the sentence "A 5 substantial body of published evidence has 6 accumulated regarding the safety of quadrivalent 7 Gardasil." 8 That's -- they are cited for that 9 particular thing. 10 Q And you go on to say "with no confirmed 11 safety problems identified to date, other than 12 syncope and skin infections." 13 A That's correct. 14 Q Correct? 15 So I just want to, if I can, mark these 16 papers, just to make sure we have them correct; 17 okay? 18 A Okay. 19 (Whereupon, Exhibit MK 8, Klein 20 Paper, was marked for 21 identification.) 22 BY MR. TOMASELLI: 23 Q I'm handing you Exhibit 8, which is the 24 Klein paper. 25 Is that true?</p>

26 (Pages 98 - 101)

<p style="text-align: right;">Page 102</p> <p>1 A Yes.</p> <p>2 Q And that's the Klein paper that you 3 referenced in your article; right?</p> <p>4 A Correct.</p> <p>5 (Whereupon, Exhibit MK 9, Chao Paper, 6 was marked for identification.)</p> <p>7 BY MR. TOMASELLI:</p> <p>8 Q Exhibit nine is the Chao paper referenced 9 in your paper; correct?</p> <p>10 A Correct.</p> <p>11 Q That's also the paper that you referenced 12 in your expert report; right?</p> <p>13 A Correct.</p> <p>14 (Whereupon, Exhibit MK 10, Arnheim 15 Dahlström Paper, was marked for 16 identification.)</p> <p>17 BY MR. TOMASELLI:</p> <p>18 Q Exhibit 10 is the Arnheim Dahlström paper 19 that is referenced in your Exhibit 7; correct?</p> <p>20 A Correct.</p> <p>21 (Whereupon, MK 11, Grimaldi-Bensouda 22 2014 Paper, was marked for 23 identification.)</p> <p>24 BY MR. TOMASELLI:</p> <p>25 Q Exhibit 11 is the Grimaldi-Bensouda 2014</p>	<p style="text-align: right;">Page 104</p> <p>1 (Whereupon, Exhibit MK 13, Scheller 2 2015 Paper, was marked for 3 identification.)</p> <p>4 BY MR. TOMASELLI:</p> <p>5 Q Exhibit 13 is the Scheller paper from 6 2015 that is referenced in Yih 2018; right?</p> <p>7 A Correct.</p> <p>8 (Whereupon, Exhibit MK 14, Naleway 9 Paper, was marked for 10 identification.)</p> <p>11 BY MR. TOMASELLI:</p> <p>12 Q Exhibit 14 is the Naleway paper that is 13 in your publication; is that right?</p> <p>14 A Correct.</p> <p>15 (Whereupon, Exhibit MK 15, 16 Grimaldi-Bensouda 2017 Paper, was 17 marked for identification.)</p> <p>18 BY MR. TOMASELLI:</p> <p>19 Q And as you noted, Exhibit 15 is a paper 20 by Grimaldi-Bensouda --</p> <p>21 MR. BAUM:Oops.</p> <p>22 MR. TOMASELLI: Sorry.</p> <p>23 BY MR. TOMASELLI:</p> <p>24 Q -- that is from 2017; correct?</p> <p>25 A Yes.</p>
<p style="text-align: right;">Page 103</p> <p>1 paper that is referenced in your paper; correct?</p> <p>2 A Correct.</p> <p>3 There are two of those. That's the first 4 one of them.</p> <p>5 Q In fact, there are three.</p> <p>6 Are you aware --</p> <p>7 A You've got --</p> <p>8 Q -- of that?</p> <p>9 A -- three of them?</p> <p>10 Q Oh, withdrawn.</p> <p>11 There are two papers --</p> <p>12 A By Grimaldi --</p> <p>13 Q -- by the --</p> <p>14 A -- -Bensouda.</p> <p>15 Q -- name of Grimaldi-Bensouda in your Yih 16 2018 paper?</p> <p>17 A I had two of them cited. Yeah.</p> <p>18 Q Okay.</p> <p>19 (Whereupon, Exhibit MK 12, 20 Langer-Gould Paper, was marked for 21 identification.)</p> <p>22 BY MR. TOMASELLI:</p> <p>23 Q Exhibit No. 12 is the Langer-Gould paper 24 that you referenced in Yih 2018; correct?</p> <p>25 A Correct.</p>	<p style="text-align: right;">Page 105</p> <p>1 Q And that is referenced in your Yih 2018 2 paper; right?</p> <p>3 A Yeah.</p> <p>4 (Whereupon, Exhibit MK 16, Feiring 5 Paper, was marked for 6 identification.)</p> <p>7 BY MR. TOMASELLI:</p> <p>8 Q Number -- Exhibit No. 16 is the Feiring 9 paper that is referenced in Yih 2018; correct?</p> <p>10 A Correct.</p> <p>11 (Whereupon, Exhibit MK 17, Miranda 12 Paper, was marked for 13 identification.)</p> <p>14 BY MR. TOMASELLI:</p> <p>15 Q And Exhibit 17 is the Miranda paper that 16 is referenced in the Yih 2018 paper; correct?</p> <p>17 A Correct.</p> <p>18 Q And in terms of the paper that you cited 19 for the same sentence where you talk about vaccine 20 doses distributed, that was a -- a paper at footnote 21 16 that is from Sukamaran, S-u-k-a-m-a-r-a-n, from 22 an ACIP meeting from 2015; is that right?</p> <p>23 A That is correct.</p> <p>24 (Whereupon, Exhibit MK 18, Dr. 25 Sukamaran's Paper Regarding HPV</p>

27 (Pages 102 - 105)

<p style="text-align: right;">Page 106</p> <p>1 Vaccine Safety, was marked for 2 identification.)</p> <p>3 BY MR. TOMASELLI:</p> <p>4 Q And to save a few trees, Exhibit 18 is 5 the report that you cited from Dr. Sukumaran 6 regarding HPV vaccine safety. It starts on page 69 7 of page 18 [sic]; right?</p> <p>8 MR. BAUM: Exhibit 18?</p> <p>9 MR. TOMASELLI: Yes.</p> <p>10 A What started where?</p> <p>11 BY MR. TOMASELLI:</p> <p>12 Q Sorry.</p> <p>13 If you turn to page 69 --</p> <p>14 A Oh okay.</p> <p>15 Q -- of Exhibit 18, can you confirm that 16 that is the Dr. Sukumaran that you referenced in 17 footnote 16 of the Lee [sic] 2018 paper?</p> <p>18 A Yes.</p> <p>19 Q Great.</p> <p>20 (Whereupon, the court reporter 21 requests clarification.)</p> <p>22 COURT REPORTER: Lee or Yih?</p> <p>23 MR. TOMASELLI: Yih. Yih.</p> <p>24 COURT REPORTER: Okay.</p> <p>25</p>	<p style="text-align: right;">Page 108</p> <p>1 Q -- 13?</p> <p>2 A Sure.</p> <p>3 Q Any one of those papers could drop out, 4 and it still holds what you said in the paper; 5 correct?</p> <p>6 A Correct.</p> <p>7 Q All right. In -- in this paper, this Yih 8 2018 paper, you say -- lost my spot. Apologize. 9 Oh. Withdrawn.</p> <p>10 So the -- the first page again --</p> <p>11 sorry -- of the Yih 2018 paper, the very, very end 12 of the first page, sir...</p> <p>13 A Let's see if I can find that.</p> <p>14 So end of the first page?</p> <p>15 Q Yes, sir.</p> <p>16 A Yup.</p> <p>17 Q It says, "More open-ended studies 18 addressing HPV vaccine safety more generally..."</p> <p>19 And then, it turns over --</p> <p>20 A Where does --</p> <p>21 Q -- to --</p> <p>22 A -- it say that?</p> <p>23 Q Are you in Yih 2018? MR. BAUM: Should be this one.</p> <p>25</p>
<p style="text-align: right;">Page 107</p> <p>1 BY MR. TOMASELLI:</p> <p>2 Q Again, by my count you -- you cited about 3 11 or 12 publications related to the safety of 4 Gardasil vaccine in your Yih 2018 paper -- right? -- 5 in that introduction?</p> <p>6 A There was at least 11. There were 7 probably more in the -- there are -- I think there 8 are more in the paper probably.</p> <p>9 Q That's a good point.</p> <p>10 The -- each of those papers cites other 11 papers, as well; right?</p> <p>12 A Of course they do. Yes.</p> <p>13 Q Yeah. The -- if you dropped any one of 14 those papers from that citation in the introduction, 15 the -- the proposition would still hold true; right?</p> <p>16 MR. BAUM: Objection. Vague.</p> <p>17 A Well, this has a substantial body. I 18 mean, there's more than those 11 papers on Gardasil.</p> <p>19 But you don't want to cite too many 20 papers. So I don't know what the definition of 21 "substantial" is. So...</p> <p>22 BY MR. TOMASELLI:</p> <p>23 Q Well, and my simple question is: You 24 could have cited nine, 10, 11, 12 --</p> <p>25 A Sure.</p>	<p style="text-align: right;">Page 109</p> <p>1 BY MR. TOMASELLI:</p> <p>2 Q Exhibit 7.</p> <p>3 A Oh, I was -- oh, I was -- I was looking 4 at Julianne Gee. Sorry. Not Yih -- Katherine Yih. 5 Sorry.</p> <p>6 Yeah. So Yih -- Katherine Yih two 7 thousand --</p> <p>8 Q -- 18. So it's Exhibit 7. I think you 9 still may have the wrong one.</p> <p>10 A Oh, that's the -- the TreeScan paper.</p> <p>11 Yeah. Okay.</p> <p>12 Q The TreeScan paper. Yeah. Okay.</p> <p>13 Withdrawn.</p> <p>14 Dr. Kulldorff, at the very bottom of this 15 2018 paper, do you see where the last line says, 16 "More open-ended" --</p> <p>17 A Okay.</p> <p>18 Q -- "studies addressing HPV vaccination 19 more generally without prespecifying income -- 20 outcomes of concern have been fewer and have been 21 somewhat limited in sample size, [number five] 22 [sic], or have tended to rely on spontaneous 23 reports" -- and you cite 17 and 18 -- "the 24 interpre -- "the interpretability of which is 25 hampered by lack of control groups and denominators,</p>

28 (Pages 106 - 109)

<p style="text-align: right;">Page 110</p> <p>1 underreporting, and reporting biases."</p> <p>2 Do you see that?</p> <p>3 A Correct.</p> <p>4 Q And in terms of the interpretation of --</p> <p>5 well, withdrawn.</p> <p>6 In terms of the last part of that</p> <p>7 sentence where the interpretability is hampered, you</p> <p>8 cite three papers there, 19 through 21; correct?</p> <p>9 A Correct.</p> <p>10 Q The paper by -- on number 19, is</p> <p>11 Shimabukuro 2015; right?</p> <p>12 A Yes.</p> <p>13 Q And the cite number 20, is a paper by</p> <p>14 Varricchio, V-a-r-r-i-c-h-i-o, from 2004; correct?</p> <p>15 A Correct.</p> <p>16 Q And then you also cite a paper by</p> <p>17 Iskander; right?</p> <p>18 A Correct.</p> <p>19 Q My understanding, based on what I've</p> <p>20 read, is -- is you cite these papers fairly</p> <p>21 frequently for the limitations of spontaneous</p> <p>22 adverse event reporting databases; is that right?</p> <p>23 A I don't remember.</p> <p>24 Q Okay.</p> <p>25 A Yes or not.</p>	<p style="text-align: right;">Page 112</p> <p>1 that is, the VAERS database -- "is to detect early</p> <p>2 warning signals and generate hypotheses about</p> <p>3 possible new vaccine adverse events or changes in</p> <p>4 frequency of known ones."</p> <p>5 Do you see that?</p> <p>6 A Yes.</p> <p>7 Q Do you agree with that?</p> <p>8 A That's certainly a function of it.</p> <p>9 Q And if you move to the right-hand side of</p> <p>10 the paper in the abstract, about five lines down, do</p> <p>11 you see that it says "VAERS data contains strong</p> <p>12 biases."</p> <p>13 Do you see that?</p> <p>14 A Yes.</p> <p>15 Q It says, "VAERS data contains strong</p> <p>16 biases. Incidence rates and relative risks of</p> <p>17 specific adverse events cannot be calculated."</p> <p>18 Do you see that?</p> <p>19 A I see that.</p> <p>20 Q And that's true?</p> <p>21 A That's true if you try to, for example,</p> <p>22 do -- of certain expected ratios. So -- because</p> <p>23 they are both underreporting and overreporting in</p> <p>24 the spontaneous reports.</p> <p>25 So if you, for example, try to take</p>
<p style="text-align: right;">Page 111</p> <p>1 (Whereupon, Exhibit MK 19, Varricchio</p> <p>2 Paper, was marked for</p> <p>3 identification.)</p> <p>4 BY MR. TOMASELLI:</p> <p>5 Q I'm going to hand you what I've marked as</p> <p>6 Exhibit 19, which is the Varricchio paper.</p> <p>7 Do you see that?</p> <p>8 A Correct. Yes.</p> <p>9 Q And that is the paper that you cited in</p> <p>10 Yih 2018; correct?</p> <p>11 A Yes.</p> <p>12 Q Now, you've obviously seen this paper</p> <p>13 before -- Varricchio 2004?</p> <p>14 A I don't remember.</p> <p>15 Q Okay. Well, let's read it.</p> <p>16 If you take a look at the abstract, four</p> <p>17 lines down, there's a statement that says "its</p> <p>18 primary function."</p> <p>19 Do you see that?</p> <p>20 A Correct.</p> <p>21 Q And by "its" they're talking about the --</p> <p>22 the VAERS database that's maintained by the FDA and</p> <p>23 the CDC; correct?</p> <p>24 A Correct.</p> <p>25 Q And it says, "Its primary function" --</p>	<p style="text-align: right;">Page 113</p> <p>1 background rates from a different study to see what</p> <p>2 is the background rate for stroke, for example,</p> <p>3 like, how many strokes are there in this -- in -- in</p> <p>4 the -- in the VAERS data.</p> <p>5 Those are not really comparable. So you</p> <p>6 cannot then calculate specific risks because of</p> <p>7 that. Because you're comparing apples and oranges,</p> <p>8 essentially.</p> <p>9 Q Fair enough.</p> <p>10 A And --</p> <p>11 A And that's one of the things that I</p> <p>12 mentioned in my report, contrary to Merck response</p> <p>13 to the -- to EMA, that they were doing -- trying to</p> <p>14 use spontaneous reports to do this of certain</p> <p>15 expecteds.</p> <p>16 And I think I's a futile thing to do.</p> <p>17 You can't do it good, so you shouldn't do it -- do</p> <p>18 it at all.</p> <p>19 Q Okay. But in terms of what -- what --</p> <p>20 what's written here, that VAERS cannot be used to</p> <p>21 calculate incidence rates and relative risks of</p> <p>22 specific adverse events, that's true?</p> <p>23 A So incidence rates, like, based on the</p> <p>24 population?</p> <p>25 Q Yes.</p>

29 (Pages 110 - 113)

<p style="text-align: right;">Page 114</p> <p>1 A Or relative risk -- 2 Q Yes. 3 A -- based on the population where you have 4 a -- background rates, for example? 5 Q Yes, sir? 6 A It should -- can -- you can just do it, 7 but it's going to be -- so, like, technically, you 8 could try to do it, and people have tried to do it. 9 But those are not reliable. And I think 10 they should not be calculated. 11 Q We'll -- we'll come to that in a second. 12 A couple lines down in the abstract, it 13 says, "Signal" -- "signals detected in VAERS should 14 be subjected to further clinical and descriptive 15 epidemiologic analysis. Confirmation in a 16 controlled study is usually required." 17 Do you see that? 18 A Correct. 19 Q And that is correct; true? 20 A Yeah. There are some exceptions. 21 For example, with the COVID vaccine, 22 there was -- the VAERS picked up a -- a -- a signal 23 of anaphylaxis. And I think that was sufficient to 24 determine using the -- the VAERS data. 25 So there are -- there are situations</p>	<p style="text-align: right;">Page 116</p> <p>1 Q And EudraVigilance is another spontaneous 2 reporting system; correct? 3 A Yes. So I think the European countries 4 have their own systems. 5 Q When we -- can you turn over to the third 6 page? 7 And do you see a part that says "Pitfalls 8 of VAERS"? 9 A Okay. 10 Q Again, you've obviously read this paper 11 before; right? 12 A I don't remember if I have or not. 13 Q Okay. Fine. 14 Under "Pitfalls of VAERS," it says, 15 "Several articles have been published since 2000 16 based on publicly available VAERS data." 17 A Yes. 18 Q And then, it says, "These papers 19 frequently fail to acknowledge important limitations 20 of the system. In several cases, despite citing 21 references that clearly outline the weaknesses of 22 passive surveillance systems, some authors 23 apparently have chosen to ignore them." 24 Do you see that? 25 A Yes.</p>
<p style="text-align: right;">Page 115</p> <p>1 where VAERS data, by itself, can be used. 2 Anaphylaxis, which is a rare but well-established 3 adverse reactions to the COVID vaccine is one 4 example of that. 5 Q If you turn over to the second page, do 6 you see a part that says "Description of VAERS"? 7 A Yup. 8 Q It says, "VAERS is a passive surveillance 9 or spontaneous reporting system." 10 Do you see that? 11 A Correct. 12 Q That is true; right? 13 A Yes. 14 Q It's not the only passive surveillance 15 system for adverse events and vaccines around the 16 world; right? 17 A Almost every country has one. 18 Q Yeah. I mean, VigiBase is one; right? 19 It's run by the WHO; correct? 20 A So VigiBase is solely global where they 21 collect from many different countries. 22 Q Right. 23 VAERS reports, actually, go into 24 VigiBase; correct? 25 A I think so. Yeah.</p>	<p style="text-align: right;">Page 117</p> <p>1 Q And they cite 32, 33, and 34. 2 A Yeah. 3 Q Correct? 4 A Yes. 5 Q Who are the authors of those papers? 6 A The first one is Guyer and Guyer. The 7 second one is Guyer and Guyer. And surprise, 8 surprise, the third one is Guyer and Guyer. 9 Q And are you aware that Guyer and Guyer 10 have published on Gardasil? 11 A I think so. Yes. 12 Q And you've never cited their work at all 13 ever. Correct? 14 A I don't remember having done so, but I 15 might have. I don't know. 16 Q When you further come down in the same 17 area that we were just looking at, it says, "When 18 these drawbacks of VAERS are taken into account..." 19 A Oh, let me just find the place, again. 20 Q Sorry. It's right where we were. 21 It says, "When these drawbacks of VAERS 22 are taken into account, many of the conclusions of 23 these studies appear unsupportable." 24 Do you see that? 25 A Yes. I see that.</p>

30 (Pages 114 - 117)

<p style="text-align: right;">Page 118</p> <p>1 Q Further down, about seven lines up, do 2 you see "Instructions to health care providers...?" 3 A Is that on the same page? 4 Q Yes, sir. 5 A Further up you said? 6 Q It's about eight lines from the bottom. 7 A Oh, okay. 8 Q It says, "Instructions to Health Care 9 procedures and consumers regarding reporting state 10 clearly that VAERS is an" -- "is interested in 11 receiving reports, even if causal relation to 12 vaccination is uncertain, consistent with the 13 purpose of VAERS in generating, not testing 14 hypotheses." 15 Do you see that? 16 A Yes. 17 Q And that is true, that VAERS and analyses 18 that are done out of VAERS, generally, are for 19 signal generation for generating hypotheses, not 20 testing them; right? 21 A I think that most used for -- for 22 generating hypothesis. But they can also be used as 23 part of the evidence for -- for hypothesis. 24 They, sort of, go into the -- the whole 25 mosaic of you -- you, typically, don't have only one</p>	<p style="text-align: right;">Page 120</p> <p>1 A That was one example. 2 Q VAERS adverse event database is 3 hypothesis-generating for events that are -- occur 4 in the background by chance; right? 5 MR. BAUM: Objection. Vague. 6 A Well, for all events, it can happen in 7 background by chance. 8 So I don't see -- I mean, so I don't see 9 distinguishing between that. That's the case for 10 all events.</p> <p>11 BY MR. TOMASELLI:</p> <p>12 Q If you go to the bottom of page 290, the 13 very bottom right, you see the paragraph that starts 14 "Attempts to use" --</p> <p>15 A On left or right?</p> <p>16 Q The -- the bottom right.</p> <p>17 A Okay.</p> <p>18 Q Do you see a paragraph that starts --</p> <p>19 A Yup.</p> <p>20 Q -- "attempts to use..."?</p> <p>21 Do you see where I am?</p> <p>22 A Yeah.</p> <p>23 Q Great.</p> <p>24 It says, "Attempts to use the VAERS data 25 to calculate internal relative risks of specific</p>
<p style="text-align: right;">Page 119</p> <p>1 study. So you have, like, when you evaluate the 2 safety of a vaccine, you have, like, a whole mosaic 3 or, like -- like a big jigsaw puzzle, since you have 4 so many pieces.</p> <p>5 Q For sure.</p> <p>6 A And -- and --</p> <p>7 Q And the --</p> <p>8 A -- the -- and --</p> <p>9 Q -- piece --</p> <p>10 A -- and the VAERS is one piece of that.</p> <p>11 Q Right.</p> <p>12 A Even if it's -- even if it's 13 signal-generating, it's still a piece of the 14 evidence, because that -- that evidence can be 15 stronger or weaker -- weaker.</p> <p>16 And once you look into it in more detail, 17 things might be stronger or weaker as you look into 18 the VAERS data more -- more carefully.</p> <p>19 Q It's fair, though, that databases like 20 VAERS and analyses out of databases like VAERS are 21 hypothesis-generating, like these authors said, not 22 hypothesis testing; right?</p> <p>23 A That's typically how they're used. But 24 they could be used, also, as evidence of causality. 25 Q In terms of anaphylaxis?</p>	<p style="text-align: right;">Page 121</p> <p>1 adverse events for a vaccine using reports for 2 another vaccine as control group raise a fifth 3 methodologic issue. Relative risks represent a 4 ratio of incidence rates. And incidence rates 5 cannot be calculated from VAERS data as previously 6 discussed."</p> <p>7 Do you see that?</p> <p>8 A Yeah.</p> <p>9 Q You agree with that; right?</p> <p>10 A No.</p> <p>11 Q And again, these are -- the authors here 12 are from the FDA and the CDC; right?</p> <p>13 A Yes. They are CDC and FDA.</p> <p>14 So it's correct that incidence rates 15 cannot be calculated from VAERS data. That is 16 correct.</p> <p>17 Q Okay. Do you --</p> <p>18 A But relative risk represents a ratio of 19 incidence rates is not necessarily true. That may 20 or may not be true, depending on the data.</p> <p>21 But the second part is true: "incidence 22 rates cannot be calculated from VAERS data as 23 previously discussed."</p> <p>24 That's true. The --</p> <p>25 Q The --</p>

<p style="text-align: right;">Page 122</p> <p>1 A -- second part of that sentence is true. 2 Q And the next sentence, "Relative 3 reporting rates might be calculated. But elevated 4 relative reporting rates calculated from VAERS data 5 may be spurious, regardless of the results of 6 statistical significance testing." 7 Correct? 8 A That is correct. 9 Q If you go down to the next paragraph, 10 read with me: "Comparisons of reported adverse 11 events between vaccines may also be faulty because 12 vaccines given within particular age ranges are 13 sometimes associated with adverse events that follow 14 background risk of illness in that age group. For 15 example, ages at which health care providers are 16 vaccinated against hep- -- hepatitis B are within 17 the age" -- I'm sorry -- "within the range when 18 multiple sclerosis and related demyelinating 19 diseases are most likely to be diagnosed." 20 Do you see that? 21 A Correct. 22 Q And that's true; right? 23 A So age is one of the potential 24 confounders when you look at VAERS data. 25 Q And if --</p>	<p style="text-align: right;">Page 124</p> <p>1 Bayesian" -- B-a-y-e-s-i-a-n -- "and neural network 2 approaches." 3 Do you see that? 4 A Correct. Yeah. I see that. 5 Q And then, if you go down further, it 6 says, "An event with a higher proportion for the 7 study vaccine than for other vaccines might be 8 considered a signal and require further study. For 9 other methods" -- sorry. 10 It then goes on to say, "The other 11 methods calculate a similar measure of 12 disproportionality." 13 Do you see that? 14 A Yes. I see that. 15 Q And so if we go down to the last three 16 lines of the paragraph, it says, "Just as with 17 relative reporting rate interpretation, PRR and 18 other data mining statistics can be biased by 19 differences in usage and reporting of adverse 20 events. Thus, elevated data mining statistics do 21 not necessarily reflect a causal relationship 22 between a vaccine and an adverse event." 23 Do you see that? 24 A I see that. 25 Q And then, it goes on to say, "PRR and</p>
<p style="text-align: right;">Page 123</p> <p>1 A Ant that's, sort of, expressed here quite 2 nicely, I think. 3 Q Yeah. And if we go down in that same 4 column to the end of that paragraph and the 5 beginning of the next one, do you see "relative 6 reporting rates"?</p> <p>7 A Yes. 8 Q It says, "Relative reporting rates from 9 VAERS should not be confused with" -- 10 (Whereupon, the court reporter 11 requests clarification.) 12 MR. TOMASELLI: Yes. 13 BY MR. TOMASELLI: 14 Q Sorry. Withdrawn. 15 The document states, "Relative reporting 16 rates from VAERS should not be confused with data 17 mining methods that attempt to identify adverse 18 events reported more commonly after one vaccine or a 19 group of vaccines than others." 20 Do you see that? 21 A Yes. 22 Q The document goes on to say, "Three data 23 mining methods are being applied increasingly to 24 medical product safety data are the proportional 25 reporting rate" -- "ratio, the PRR; empiric</p>	<p style="text-align: right;">Page 125</p> <p>1 other data mining statistics should not be 2 interpreted or presented as relative risks of 3 specific vaccine adverse events." 4 Do you see that? 5 A Yes. 6 Q "Such statistics should be used only as a 7 hypothesis generation tool and are evaluated in the 8 same manner as other hypotheses generated by VAERS." 9 Do you see that? 10 A I see that. 11 Q Do you agree with that? 12 A Not all of it. No. A lot of it, I agree 13 with. Not all of it. 14 Q Do you agree that disproportionality 15 methods are signal generation methods? 16 A They are used for signal generations and 17 are an important tool for signal generation. 18 Q Say that again? 19 A They are an -- are an important tool for 20 signal generation. 21 Q I think we're on the same page. 22 Disproportionality analyses are an 23 important tool for signal generation, but they are 24 signal generation methods; correct? 25 A They cannot -- they should also be used</p>

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<p style="text-align: right;">Page 126</p> <p>1 as part of the evaluation. So they're not only 2 signal generations tools. They can also be used for 3 part of es- -- establishing a causal relationship. 4 And in rare cases, like the one I gave 5 you for anaphylaxis, they can, by themself, be used. 6 But most of the times you use it, you need 7 additional data, also.</p> <p>8 Q Do you agree that disproportionality 9 statistics can be biased by differences in usage and 10 reporting rates?</p> <p>11 A For example, there could be issues of age 12 so that -- so I -- I agree with that. Because you 13 could have age that if -- if the vaccine is given in 14 a particular age group, and then, the comparative 15 vaccine is a different age group, or they have a 16 different age distribution, and then, the -- the 17 outcome of interest also has some kind of an age 18 curve, then, they can bias it in either directions, 19 depending on how those age curves are.</p> <p>20 (Whereupon, Exhibit MK 20, 21 Shimabukuro 2015 Paper, was marked 22 for identification.)</p> <p>23 BY MR. TOMASELLI:</p> <p>24 Q I'm handing you what I've marked as 25 Exhibit 20, which is a paper by Shimabukuro,</p>	<p style="text-align: right;">Page 128</p> <p>1 Shimabukuro paper; right? 2 A Yes. 3 Q And I'd like you to turn to page 4401, 4 section 6.2, "Disproportionality Analysis"? 5 A Correct. Yeah. 6 Q Five lines down, do you see that it says, 7 "VAERS lacks information on total number of 8 individuals vaccinated and total number who 9 experience an adverse event, as well as incidence of 10 adverse events in unvaccinated individuals." 11 Do you see that? 12 A That is correct. And that's true. 13 Q Okay. And then, toward the bottom of 14 that column, the last paragraph starts, 15 "Disproportionality analyses complements..." 16 Do you see that? 17 A Okay. Yes. 18 Q It says, "Disproportionality analyses 19 complements clinical reviews and other analyses to 20 identify adverse events that may be more frequently 21 associated with a particular vaccine." 22 Do you see that? 23 A Yes. 24 Q And that's true; right? 25 A Yeah. I think that's true.</p>
<p style="text-align: right;">Page 127</p> <p>1 S-h-i-m-a-b-u-k-u-r-o, from 2015; do you see that? 2 A Yes. 3 Q This is a -- another one of the papers 4 that you cited in Yih 2018 for limitations of 5 spontaneous reports; correct? 6 A I think that was one of them. Yeah. 7 Let me ask -- make sure they're on -- or 8 I -- I mean, I trust you. If you say so, I trust 9 you. So -- or do you want me to confirm it? 10 Q I mean, we -- I thought we went over 11 them, and so I was just confirming. 12 But if you want to make sure that 13 Shimabukuro is number 19, that's great. 14 A And this was in the Yih paper of 2018? 15 Q That's correct. 16 MR. BAUM: Is that -- is that 17 Exhibit 7? 18 MR. TOMASELLI: That's correct. 19 THE WITNESS: Oh, it's Exhibit 7? 20 Oh, okay. 21 Oh, here it is. 22 A Yes. That's cited in the Yih paper from 23 2018. 24 BY MR. TOMASELLI: 25 Q Okay. And so Exhibit 20 is indeed the</p>	<p style="text-align: right;">Page 129</p> <p>1 And I think it's an important -- 2 important part of that -- a very important 3 compliment. 4 Q The next sentence states, "A result that 5 exceeds a prespecified statistical alerting 6 threshold might warrant further evaluation, such as 7 clinical review of reports, but does not 8 definitively demonstrate a true increased incidence 9 of an adverse event, a Causal association, or a 10 safety problem." 11 Do you see that? 12 A Yes. 13 Q And that is true, that just because you 14 have disproportionality of reporting, that does not 15 mean that there is a safety problem; correct? 16 A There could be various biases confounding 17 that has to be take -- taken into account when 18 doing, sort of, a -- a evaluation of everything. 19 Q When the VAERS system showed 20 disproportionality of venous thromboembolism events, 21 you've had several papers investigating that signal; 22 right? 23 A Correct. 24 Q A signal of disproportionality does not 25 mean that adverse events are occurring more often</p>

<p style="text-align: right;">Page 130</p> <p>1 than what would be expected in an unvaccinated 2 population; right?</p> <p>3 A That might be the true. Yes. Correct.</p> <p>4 Q Your -- your -- your venous 5 thromboembolism analysis showed that to be the 6 case -- right? -- that you can have 7 disproportionality reporting, and yet, there not be 8 a situation where that event is occurring more than 9 in an unvaccinated population; right?</p> <p>10 A So the VTE, I think, is a perfect example 11 of how things should have been done -- should -- how 12 things should be do -- done. You have --</p> <p>13 Q Can you answer my question first, and 14 then, you can say that?</p> <p>15 So my question, first, is that: Just a 16 simple finding of disproportionality in VAERS does 17 not mean that there's actually an increased risk in 18 an unvaccinated population; right?</p> <p>19 A Correct. It doesn't necessarily mean 20 that.</p> <p>21 Q And then, tell me why your VTE example is 22 a perfect example as you stated.</p> <p>23 A So I think it's a very good example.</p> <p>24 There was a concern. And when Gardasil came out, I 25 think that was the first major concern about the</p>	<p style="text-align: right;">Page 132</p> <p>1 think that was a -- a good example of -- of how -- 2 how it should be done when you -- when you have a -- 3 vaccine safety.</p> <p>4 And it's an example that, if you care 5 about vaccines, I think it's very important to do 6 so. Whatever you find, it's very important to do 7 so. Because if you find nothing, you want to have 8 solid evidence that there's not a problem.</p> <p>9 There are other cases where we have -- 10 find problems with a vaccine. And then, that's 11 important to fig- -- to -- to -- to find, also, 12 whether you want to withdraw the vaccine, like 13 RotaShield, or whether you want to keep it on the 14 market, like with RotaTeq.</p> <p>15 It's -- it's important to know what's 16 going on with the vaccine and to very solidly and 17 well doing that. So that is, I think, my 18 disappointment with Gardasil and POTS, that those 19 solid studies hasn't been made.</p> <p>20 Q Well, in fairness, we talked earlier, you 21 have actually not reviewed all of the studies 22 related to Gardasil and POTS in your expert report; 23 right?</p> <p>24 A Correct.</p> <p>25 Q Okay. And so working off of this example</p>
<p style="text-align: right;">Page 131</p> <p>1 vaccine.</p> <p>2 And it was then evaluated in different 3 manners. It was evaluated using the -- I think, the 4 rapid cycle analysis. And there was nothing 5 statistically significant. But there was some -- 6 maybe something there, so we wouldn't exclude it.</p> <p>7 And then, we have the subsequent paper 8 that I wrote -- that -- what I was a co- -- coauthor 9 on. And I think there were other publications, as 10 well.</p> <p>11 And I think it's a perfect example where 12 there was a concern, both in terms of the data, but 13 also, in terms of the public, in terms of parents. 14 And by doing proper studies -- there was very solid 15 proper studies -- those concerns were laid to rest.</p> <p>16 And I think it's a -- it -- it was -- 17 this is the way that vaccine safety science should 18 operate. You have various methods to -- to take 19 potential problems. And then, you do very good 20 studies to either confirm those problems or put them 21 to rest with good, solid statistical methods.</p> <p>22 So from my perspective, the Gardasil and 23 the VTE is a success story for vaccine safety 24 research. A lot of effort went into it, a lot of 25 good studies, good scientists was doing it. And I</p>	<p style="text-align: right;">Page 133</p> <p>1 of VTE -- well, withdrawn.</p> <p>2 A signal of disproportionality in 3 reporting does not mean that there's actually an 4 association of increased risk with the vaccine; 5 correct?</p> <p>6 A Correct.</p> <p>7 You have to explore that.</p> <p>8 Q A signal of disproportionality does not 9 mean that the vaccine in question actually causes 10 the event; right?</p> <p>11 MR. BAUM: Objection. Vague.</p> <p>12 A So -- so -- so in some cases like 13 anaphylaxis, I think, that was the -- that was 14 enough.</p> <p>15 But in other cases, there is a signal, 16 and it might not be true -- it might not be causal. 17 So you -- you have to judge this from time to time.</p> <p>18 BY MR. TOMASELLI:</p> <p>19 Q That's my point --</p> <p>20 A Yeah.</p> <p>21 Q -- is -- that -- that's my simple point 22 is that a signal disproportionality, by itself, 23 doesn't mean --</p> <p>24 A It doesn't automatically. Correct.</p> <p>25 Q -- does not mean that that the vaccine</p>

<p style="text-align: right;">Page 134</p> <p>1 causes the event; right?</p> <p>2 A Doesn't automatically mean that.</p> <p>3 Correct.</p> <p>4 Q A signal of disproportionality in</p> <p>5 reporting actually doesn't mean, by itself, that</p> <p>6 there's a safety problem at all; right?</p> <p>7 A For -- in some cases, by itself, it could</p> <p>8 mean that. But not automatically. Yes.</p> <p>9 Because there's a signal doesn't</p> <p>10 automatically mean that there is a causal problem.</p> <p>11 But there are situations where such a signal, by</p> <p>12 itself, is enough to establish causal relationship.</p> <p>13 And I gave the example of anaphylaxis and the COVID</p> <p>14 vaccine, for example.</p> <p>15 Q Yeah. And -- and that is the -- that is</p> <p>16 the example that you've been giving a lot, is that</p> <p>17 there are times where an event is so immediate and</p> <p>18 so rare that -- that you can judge that.</p> <p>19 But in terms of other things, that's --</p> <p>20 that's actually not true; right?</p> <p>21 Other events, it's not true?</p> <p>22 A Sometimes, it's true. Most of the time,</p> <p>23 it's not.</p> <p>24 Q All right. Most of the time?</p> <p>25 A Most of the time, it is -- is not a --</p>	<p style="text-align: right;">Page 136</p> <p>1 MR. TOMASELLI: -- to go.</p> <p>2 THE WITNESS: -- point. But --</p> <p>3 MR. TOMASELLI: But it's --</p> <p>4 THE WITNESS: -- if you --</p> <p>5 MR. TOMASELLI: -- totally up --</p> <p>6 THE WITNESS: -- want to --</p> <p>7 MR. TOMASELLI: -- to you.</p> <p>8 THE WITNESS: -- go a little bit</p> <p>9 more, that's fine. But we can always</p> <p>10 take a break now -- whatever it, sort of,</p> <p>11 suits -- fits you with your -- it's --</p> <p>12 it's good to, sort of, to keep the</p> <p>13 logical things together.</p> <p>14 MR. TOMASELLI: Sounds good.</p> <p>15 COURT REPORTER: Could we take a</p> <p>16 break now?</p> <p>17 MR. TOMASELLI: Yeah. Sure.</p> <p>18 THE VIDEOGRAPHER: The time is 11:30</p> <p>19 a.m. And we're off the record.</p> <p>20 (Whereupon, there was a recess taken</p> <p>21 from 11:29 p.m. to 11:46 a.m.)</p> <p>22 THE VIDEOGRAPHER: The time is</p> <p>23 11:46 a.m. and we are on the record.</p> <p>24 BY MR. TOMASELLI:</p> <p>25 Q Are you ready to proceed --</p>
<p style="text-align: right;">Page 135</p> <p>1 you -- you have to do further investigation. You</p> <p>2 have to have complementary -- complementary in --</p> <p>3 information.</p> <p>4 Q Let me see if we can agree on this.</p> <p>5 Withdrawn.</p> <p>6 Most of the time, a signal of</p> <p>7 disproportionality in reporting does not mean</p> <p>8 there's a safety problem at all.</p> <p>9 It needs to be further investigated?</p> <p>10 A Correct.</p> <p>11 Q Okay.</p> <p>12 A Finally, we agree.</p> <p>13 MR. TOMASELLI: Do you want to take</p> <p>14 a break?</p> <p>15 I -- I just -- I mean --</p> <p>16 MR. BAUM: It's been a while. We</p> <p>17 could probably do a break.</p> <p>18 MR. TOMASELLI: You want a break?</p> <p>19 I just -- I've, kind of, had you</p> <p>20 sitting in there. I'd --</p> <p>21 THE WITNESS: At -- at --</p> <p>22 MR. TOMASELLI: -- I mean --</p> <p>23 THE WITNESS: -- at -- at --</p> <p>24 MR. TOMASELLI: -- I'm happy --</p> <p>25 THE WITNESS: -- at some --</p>	<p style="text-align: right;">Page 137</p> <p>1 A Yes.</p> <p>2 Q -- Dr. Kulldorff?</p> <p>3 A Thank you.</p> <p>4 Q Great.</p> <p>5 The exhibit that you got there in front</p> <p>6 of you, the Shimabukuro 2015 paper, if you can turn</p> <p>7 to the next page, there's a section number eight</p> <p>8 that says, "What are the limitations of VAERS?"</p> <p>9 Do you see that?</p> <p>10 A Yes.</p> <p>11 Q It says, "Like all spontaneous public</p> <p>12 health reporting system, VAERS has limitations,</p> <p>13 VAERS is subject to reporting bias, including</p> <p>14 underreporting of adverse events, especially common</p> <p>15 and mild ones, and stimulating reporting, which is</p> <p>16 elevated reporting that might occur in response to</p> <p>17 intense media attention and increased public</p> <p>18 awareness, such as during the 2009 [sic] H1N1</p> <p>19 pandemic influenza vaccine -- vaccination program."</p> <p>20 Do you see that?</p> <p>21 A Yes, I see that.</p> <p>22 Q It is true that a limitation of VAERS is</p> <p>23 that there can be stimulated reporting, such as</p> <p>24 elevated reporting, when there's intense media</p> <p>25 attention around a vaccine; right?</p>

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<p style="text-align: right;">Page 138</p> <p>1 A That is true. 2 Q That's called reporting bias? 3 A That can generate reporting bias, yes. 4 Q Sorry. I -- can you say that again? 5 A That can create reporting bias, yeah. 6 Q Okay. And I think you said in your 7 report, "with VAERS data, one must always be 8 concerned with reporting bias." 9 Is that right? 10 A Correct. 11 Q What is reporting bias, in your words? 12 A If some people are more prone to -- so -- 13 so with spontaneous reports, they are reported 14 spontaneously by a physician, a nurse, a patient, a 15 parent, or etc. So who, then, actually reports 16 something? 17 So if something happens, some people 18 report it and some people will not report it. 19 So reporting bias is if there are 20 different tendencies or different probabilities or 21 different likelihood of it being reported under 22 certain set of circumstances versus another. 23 For example, it might be more likely to 24 report it for one vaccine versus for another 25 vaccine. It could be -- it can be more likely</p>	<p style="text-align: right;">Page 140</p> <p>1 reporting bias; true? 2 A Different things can create reporting 3 bias. If -- 4 Q We are in agreement? 5 A Yes. 6 Q And does reporting bias matter in 7 disproportionality analyses? 8 A It can, yes. 9 Q And how -- 10 A And I think that is listed in my report. 11 Actually, I mentioned it in my report. 12 Q Right. And how can disproportionality of 13 reporting or reporting bias affect a 14 disproportionality analysis? 15 A It can change the reporting odds ratios 16 or the proportional reporting ratio -- 17 (Whereupon, the court reporter 18 requests clarification.) 19 BY MR. TOMASELLI: 20 Q You've got to slow down. Sorry. 21 A Sorry. 22 It can affect the -- the estimates of the 23 reporting odds ratios or the proportion of reporting 24 ratios, whichever one it's using, either up or down. 25 Q And in your report when you discussed</p>
<p style="text-align: right;">Page 139</p> <p>1 reported one year versus another year. This can 2 create certain biases also. 3 Q Is it -- is it true that if there's 4 something in the world, whatever that is, that makes 5 people more likely to report events to VAERS 6 regarding one vaccine versus another vaccine, that's 7 a reporting bias? 8 A That can create a reporting bias. 9 Q Okay. And, for example, newspapers, TV 10 coverage, internet, social media, those are -- those 11 all could be sources of reporting bias; right? 12 A They could cause the reporting bias. 13 So one example, for example, is the COVID 14 vaccine. There was a lot of discussions about that. 15 So then maybe the reporting for the COVID vaccine is 16 different from other vaccines. 17 So that's why maybe you want to exclude 18 the COVID vaccine if you study some other vaccine, 19 because the COVID might be some special -- they must 20 sort of operate differently. So you can be 21 concerned about that. 22 Q Well, notoriety of any kind, good or 23 bad -- 24 A It could be -- 25 Q -- related to a vaccine can create</p>	<p style="text-align: right;">Page 141</p> <p>1 Dr. -- I'm sorry. Withdrawn. 2 In your report, when you discussed 3 Ms. Tomljenovic's disproportional analysis, you said 4 that it's more difficult to judge reporting bias; is 5 that true? 6 A I don't have exact -- my wording, so what 7 page is that on? 8 Q Twenty-five. 9 A Because I know I talked about it and 10 wrote about it. 11 Yeah. So I said that in the -- for 12 the -- for the Gardasil and the POTS and the POI 13 analysis that Dr. Tomljenovic did, there might be 14 bias because of -- it could be because of age. But 15 since the -- the -- the reporting odds ratios are so 16 large for POTS and POI, they were probably changed a 17 little bit, yes, for age but it's not -- I think 18 it's unlikely that they were changed a lot and go 19 away. 20 Q Okay. We are not talking about age -- 21 A But -- 22 Q -- we are talking -- 23 A But -- 24 Q -- about -- 25 A Yes.</p>

<p style="text-align: right;">Page 142</p> <p>1 Q -- reporting bias; right?</p> <p>2 A But -- but then I think for -- for 3 reporting bias, that's more difficult to judge than 4 age.</p> <p>5 Q So --</p> <p>6 A Age is more easy to understand than -- 7 than the reporting bias. So the reporting bias is 8 more difficult to get a grip on than the age bias -- 9 the potential age bias.</p> <p>10 Q And that was my question to you.</p> <p>11 A Yeah.</p> <p>12 Q Is that you admitted in your report that 13 it's more difficult to judge the reporting bias for 14 disproportionality analysis?</p> <p>15 A Compared to age, yes.</p> <p>16 Q And to be clear, as part of your work in 17 this case, you did not undertake a search of any 18 kind to see if there was reporting bias with 19 Gardasil; right?</p> <p>20 A I talked about the reporting bias -- so I 21 didn't do any research on my own of any kind in this 22 analysis. I talked about the reporting bias and 23 I -- I mentioned that I think it was a good idea 24 for -- what Tomljenovic did is to -- to -- with the 25 smaller sample size on the earlier data before there</p>	<p style="text-align: right;">Page 144</p> <p>1 by two contingency table.</p> <p>2 Do you see where I am?</p> <p>3 A Yeah.</p> <p>4 Q About five or six lines down, it starts 5 "because VAERS data do not."</p> <p>6 Do you see --</p> <p>7 A Okay.</p> <p>8 Q -- that?</p> <p>9 Do you see that?</p> <p>10 A Yes.</p> <p>11 Q The statement is, "Because VAERS data do 12 not include an unvaccinated comparison group..."</p> <p>13 Now, that's true, right? VAERS data do 14 not include an unvaccinated comparison group?</p> <p>15 A That is true.</p> <p>16 Q Okay. It goes on to say, "Because VAERS 17 data do not include an unvaccinated comparison 18 group, it is not possible to calculate and compare 19 rates of adverse events in vaccinated versus 20 unvaccinated individuals and determine if 21 vaccination is associated with an increased risk of 22 an adverse event."</p> <p>23 Do you see that?</p> <p>24 A Yeah, I see that. Yes.</p> <p>25 Q And that is indisputably a true</p>
<p style="text-align: right;">Page 143</p> <p>1 were any media attention for these things.</p> <p>2 So by doing that small -- you get smaller 3 sample size, you get much wider confidence interval, 4 but you still see the same tendency of results, the 5 same axis in those smaller samples from the -- early 6 on. And I think that was a very important, you can 7 call it a sensitivity analysis, that Dr. Tomljenovic 8 did.</p> <p>9 Q Your assumption, in looking at her 10 analysis is that prior to 2013, there was not 11 reporting bias with respect to Gardasil; correct?</p> <p>12 A There can still be some reporting bias 13 for a variety of reasons. But the major concern, I 14 think, with the reporting bias if you have major 15 media attention or other type of public attention to 16 the things.</p> <p>17 Q And that's my question to you, is that 18 you did not undertake any analysis in this case or 19 in your expert report to see what the media 20 attention actually was around Gardasil at any -- at 21 any time?</p> <p>22 A I -- I did not mention that particularly 23 in this report of -- that.</p> <p>24 Q If we go back to Shimabukuro 2015, same 25 page, right-hand column this time. So below the two</p>	<p style="text-align: right;">Page 145</p> <p>1 statement; right?</p> <p>2 A No.</p> <p>3 So the -- there are three parts of that 4 sentence: "Because VAERS data do not include an 5 unvaccinated comparison group," that is true.</p> <p>6 The second part: "It is not possible to 7 calculate and compare rates of adverse events in 8 vaccinated versus unvaccinated individuals" -- that 9 is also true -- "and determine if vaccination is 10 associated with an increased risk of an adverse 11 events [sic]," that is sometimes true and 12 sometimes -- sometimes you can and sometimes you 13 cannot.</p> <p>14 Q Well, if that question of an association 15 of an increased risk over an unvaccinated 16 population, that is true; right?</p> <p>17 MR. BAUM: Objection.</p> <p>18 You --</p> <p>19 A No. You -- it's true that it's not a 20 comp- -- it's not possible -- it's -- it's not 21 possible to calculate and compare rates of adverse 22 events in vaccinated versus unvaccinated individuals 23 because in VAERS data -- so people try to do that 24 using these observed or expected, that Merck did in 25 their -- in their response to EMA, but in my view</p>

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<p style="text-align: right;">Page 146</p> <p>1 that's not possible to do because those background 2 rates are so uncertain.</p> <p>3 But you can do the disproportionality 4 analysis of various types, whether it's reporting 5 odds ratios or pro- -- or proportional reporting 6 ratios or the empirical Bayes gamma-Poisson 7 shrinkage, you --</p> <p>8 (Whereupon, the court reporter 9 requests clarification.)</p> <p>10 THE WITNESS: Sorry. Pardon?</p> <p>11 A -- the empirical Bayes gamma-Poisson 12 shrinkage.</p> <p>13 So using those, you can -- that you -- 14 you can help determine if vaccination is associated 15 with an increased risk of an adverse -- adverse 16 event.</p> <p>17 BY MR. TOMASELLI:</p> <p>18 Q VAERS -- VAERS reports -- the VAERS 19 database does not contain unvaccinated individuals; 20 right?</p> <p>21 A That is correct.</p> <p>22 Q All right.</p> <p>23 A Everybody has been vaccinated.</p> <p>24 Q The next page of Shimabukuro 2015, page 25 4403, left side, the paragraph above "Closing</p>	<p style="text-align: right;">Page 148</p> <p>1 Q "...which as expected, increased as 2 uptake of Gardasil [sic] vaccine increased following 3 licensure in 2006."</p> <p>4 Do you see that?</p> <p>5 A Yes, I see that.</p> <p>6 Q "However, post-licensure epidemiologic 7 studies have consistently demonstrated the safety of 8 Gardasil [sic]."</p> <p>9 Do you see that?</p> <p>10 A I see that.</p> <p>11 Q They cite 45 through 51 for that; 12 correct?</p> <p>13 A Correct.</p> <p>14 Q And -- and then it goes on to say, 15 "...confirming the limitations of passive 16 surveillance systems like VAERS."</p> <p>17 Do you see that?</p> <p>18 A Yes, I see that.</p> <p>19 Q All right. And in terms of the cites 45 20 through 51, where the authors say that they 21 consistently demonstrate the safety of Gardasil 22 vaccine, 49 -- 45 through 51, those sites are a lot 23 of the same papers that you cited in Yih, 2018; 24 correct?</p> <p>25 A Yes.</p>
<p style="text-align: right;">Page 147</p> <p>1 thoughts."</p> <p>2 Are you with me?</p> <p>3 A Yes.</p> <p>4 MR. BAUM: Do you mean the paragraph 5 above -- above it? Like, "The relatively 6 rapid"?</p> <p>7 MR. TOMASELLI: That's where I was 8 going.</p> <p>9 MR. BAUM: Okay.</p> <p>10 MR. TOMASELLI: Withdrawn.</p> <p>11 BY MR. TOMASELLI:</p> <p>12 Q That paragraph states, "The relatively 13 rapid increase in numbers of reports to VAERS 14 following the introduction and initial uptake of a 15 new vaccine, an expected occurrence has been 16 misinterpreted as an -- as actual increases in the 17 incidence of adverse events and vaccine-related 18 risk."</p> <p>19 Do you see that?</p> <p>20 A Yes.</p> <p>21 Q It goes on to say, "This has been the 22 case where VAERS reports following quadrivalent 23 human papillomavirus [HPV4] [sic] vaccination..."</p> <p>24 That's Gardasil, right?</p> <p>25 A That is Gardasil.</p>	<p style="text-align: right;">Page 149</p> <p>1 Q One of those is Gee, 2011; right?</p> <p>2 A Yes.</p> <p>3 Q One of those is Chao, 2012; right?</p> <p>4 A Yes.</p> <p>5 Q One of those is Klein, 2012; right?</p> <p>6 A Yes.</p> <p>7 Q And then, of course, we have papers from 8 Arnheim-Dahlström, Grimaldi-Bensouda, and Scheller; 9 right?</p> <p>10 A Yes.</p> <p>11 Q Okay. If we come back to your Yih, 2018 12 publication, there's a discussion section on page 13 1274.</p> <p>14 A Oh, let's see. Is this the one?</p> <p>15 Q Tell me when you are there?</p> <p>16 A Okay. I have that paper now.</p> <p>17 Q Great.</p> <p>18 A Which page?</p> <p>19 Q 1274, discussion.</p> <p>20 A Yes.</p> <p>21 Q In the last sentence of the first full -- 22 the second full paragraph, you say, "In view of the 23 statistical power, the fact that only two categories 24 of adverse events were found from more than 7,000 25 leaves and branches of the hierarchical tree,</p>

<p style="text-align: right;">Page 150</p> <p>1 neither one of which was unexpected, provides 2 reassurance about both the vaccine," that's 3 Gardasil, "and the TreeScan conditional temporal 4 TreeScan method."</p> <p>5 Do you see that?</p> <p>6 A Yes. I --</p> <p>7 Q And --</p> <p>8 A -- see that.</p> <p>9 Q -- and you agree with that, right?</p> <p>10 A Yes, I agree with that.</p> <p>11 Q Okay. And then it goes on to say, "Three 12 adverse events that have drawn the attention of 13 public health authorities in relation to" -- for 14 HPV, "are complex regional pain syndrome, POTS, and 15 Guillain-Barre syndrome."</p> <p>16 Right?</p> <p>17 A That is correct.</p> <p>18 And we make a very important point here 19 and that is that, for example, CRPS and POTS, those 20 are not easily defined using the ICD system. So 21 any -- any epidemiological study, including this 22 paper, that are sort of based on the ICD -- ICD 23 codes, whether it's ICD-9 or ICD-10 codes, will have 24 a hard time picking up things about these systems.</p> <p>25 So, for example, it says that POTS is the</p>	<p style="text-align: right;">Page 152</p> <p>1 A No. I think what we are pointing out 2 here is that it provides evidence for many other 3 outcomes, but we have -- for these three -- for 4 these particular ones, it does not because the tree 5 doesn't fit in with -- neither the tree nor the ICD 6 codes fits in with -- with the definitions. These 7 are syndromes that are more fuzzily, sort of, 8 defined, in the sense that they can affect different 9 parts of the -- of the body.</p> <p>10 So that's where VAERS data has an 11 advantage over electronic health records or 12 insurance claims data, which is what this is based 13 on, in the sense that when you have a spontaneous 14 report it can actually define things much more 15 flexibly. Because whatever you feel, whatever 16 strange things or whatever combination of symptoms 17 you have, you can write that down in the VAERS 18 report or you -- your physician do it.</p> <p>19 So it's very -- flexibility of how you 20 can define symptoms. When you -- once you are based 21 on ICD codes, there are certain categories. And for 22 some things, like stroke for example, that's a very 23 good category, it's very obvious. It's not a 24 problem.</p> <p>25 Seizures is a little bit of fuss in it</p>
<p style="text-align: right;">Page 151</p> <p>1 heterogenous and potentially debilitating autoimmune 2 disorder whose symptoms can include dizziness --</p> <p>3 (Whereupon, the court reporter 4 requests clarification.)</p> <p>5 A POTS is a heterogenous and potentially 6 debilitating autoimmune disorder whose symptoms can 7 include dizziness, nausea, fatigue, palpitations, 8 weakness, sweating, and sleeping disorder.</p> <p>9 BY MR. TOMASELLI:</p> <p>10 Q Okay. Let me just stop you there.</p> <p>11 First it says autonomic disorder --</p> <p>12 correct? -- not autoimmune disorder; right?</p> <p>13 A Autonomic. Yes. Correct.</p> <p>14 Q Okay.</p> <p>15 A I'm sorry. That was my fault.</p> <p>16 Q No problem. No worries.</p> <p>17 Secondly, you can confirm that your 18 TreeScan of those 7,000 leaves and branches does 19 include things like dizziness, fatigue, 20 palpitations, tachycardia, weakness, sweating, and 21 sleeping disorders; correct?</p> <p>22 A At least some of them.</p> <p>23 Q Okay. And it is true that this study 24 does provide some evidence -- right? -- related to 25 POTS and CRPS and other disorders; correct?</p>	<p style="text-align: right;">Page 153</p> <p>1 but it's not -- you can have febrile seizures and 2 other seizures.</p> <p>3 But for POTS and CRPS, what we are 4 pointing out in the paper here, me and my coauthors, 5 is that there is less clarity or less correspondence 6 between ICD codes and -- and these two syndromes. 7 So whenever you use then electronic health records 8 or insurance claims data, that are biased based on 9 these codes, it gets much more difficult compared to 10 a VAERS data where you can actually -- the -- where 11 people can define them as they want.</p> <p>12 So that means also that, for example, 13 the -- the papers that has been using electronic 14 health records, not just this one, because --</p> <p>15 (Whereupon, the court reporter 16 requests clarification.)</p> <p>17 A Using electronic health records or 18 insurance claims data, and not just this -- this 19 paper that I wrote or other people I wrote -- papers 20 I wrote but also, for example, some of the Danish 21 work. To really get to the bottom of POTS, you have 22 to do short reviews.</p> <p>23 You can still identify --</p> <p>24 (Whereupon, the court reporter 25 requests clarification.)</p>

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<p style="text-align: right;">Page 154</p> <p>1 A Short review, medical short review. 2 So you can still -- you can 3 still identify sort of potential cases of CRPS or 4 POTS or POI. 5 But then to get -- to get the sort of the 6 right definition, you have to do medical short 7 review if you use these electronic health records -- 8 BY MR. TOMASELLI: 9 Q Okay. 10 A -- to actually get to the precise -- 11 precise definition and actually sort of do a proper 12 evaluation of what was found using those spontaneous 13 reports. 14 Q Okay. Couple things on -- 15 A Yeah. 16 Q -- on spontaneous reports. Number one, 17 they do not all come from physicians; correct? 18 A Correct. 19 Q And very simply, the spontaneous reports 20 that are in Ms. Tomljenovic's analysis were not 21 medically reviewed; correct? 22 MR. BAUM: Objection. Can you -- 23 it's Dr. Tomljenovic. Right? 24 MR. TOMASELLI: I don't know that 25 she has -- does she? Is she a doctor?</p>	<p style="text-align: right;">Page 156</p> <p>1 review, which is different. 2 Q Okay. In terms of doctors looking at the 3 cases of POTS, that's occurred in the medical 4 literature; correct? 5 A So they have, on some of the papers on 6 spontaneous reports for POTS and Gardasil, done a 7 clinical review of the VAERS -- 8 Q That's -- 9 A -- report -- 10 Q That's what we are talking about? 11 A -- but -- 12 No. 13 But they have not done medical short 14 reviews going to the medical shorts. That I have 15 not seen. 16 Q They looked at the medical records that 17 were available. 18 A They looked at the VAERS reports. 19 Q No. They looked -- and the medical 20 records that were available. Aren't you aware of 21 that? 22 A I'm not aware of that, no. 23 Q Okay. So you don't know what the Arana 24 publication and the Shimabukuro publication did? 25 You don't know what records they had available to</p>
<p style="text-align: right;">Page 155</p> <p>1 MR. BAUM: She's got a Ph.D. 2 MR. TOMASELLI: Okay. I don't know 3 how she prefers to be called. 4 Would you like me to call her 5 doctor? 6 MR. BAUM: Yeah. 7 MR. TOMASELLI: Okay. Withdrawn. 8 BY MR. TOMASELLI: 9 Q In Dr. Tomljenovic's analysis, she nor 10 you did a medical review of those cases; correct? 11 A She did not do a medical review of the 12 cases. 13 Q And neither did you? 14 A Of course not. 15 Q Okay. And in terms of people who have 16 looked at POTS cases in the spontaneous adverse 17 event world, there are some people who have done 18 clinical reviews of those cases; correct? 19 Just -- it's a yes or no, do you know? 20 A What do you mean by clinical review? 21 Q Well, I'm talking about doctors looking 22 at the spontaneous adverse event reports. Do you 23 recall that that's occurred? 24 A So there have been -- done clinical 25 reviews, but I'm not aware of doing medical short</p>	<p style="text-align: right;">Page 157</p> <p>1 use? 2 A They did clinical reviews of the VAERS 3 reports. They do not mention doing short review, 4 medical short review. 5 Q Well, you -- did you look at the Wodi 6 paper, for example, in POI where the FDA and CDC 7 looked at all the information that was available 8 including medical records? Did you not look at 9 that? 10 A I looked at the ones for POTS for Arana 11 and Shimabukuro, and they did not medical short 12 review. They don't mention medical short review in 13 those papers. 14 Q Okay. Down here in -- in Yih 2018, 15 bottom left, five lines up you say, "In 2015, the 16 European medicines agency pharmacovigilance risk 17 assessment committee completed a detailed scientific 18 review and concluded that the evidence did not 19 support a causal link between HPV vaccines and CRPS 20 or POTS." 21 Do you see that? 22 A I see that. 23 Q You cited number 35 there; correct? 24 A Correct. 25 Q And that is the EMA PRAC's assessment</p>

<p style="text-align: right;">Page 158</p> <p>1 report; correct?</p> <p>2 A That is correct.</p> <p>3 (Whereupon, Exhibit MK 21, November</p> <p>4 2015 EMA PRAC Assessment Report, was</p> <p>5 marked for identification.)</p> <p>6 BY MR. TOMASELLI:</p> <p>7 Q Exhibit 21 is the November 2015 EMA PRAC</p> <p>8 assessment report that you cited in Yih 2018;</p> <p>9 correct?</p> <p>10 A That is correct.</p> <p>11 Q And have you read that report, cover to</p> <p>12 cover, before?</p> <p>13 A I have read the report.</p> <p>14 Q Is it in your materials reviewed list or</p> <p>15 your expert report?</p> <p>16 A It might be.</p> <p>17 Q But you've read --</p> <p>18 A It's not --</p> <p>19 Q -- the whole thing?</p> <p>20 A It's not in my expert report. It's not</p> <p>21 cited in my expert report.</p> <p>22 Q Okay. But you've read the whole thing,</p> <p>23 all 40-some pages of it; correct?</p> <p>24 A I read, certainly, large parts of it.</p> <p>25 Q All right. And you called this EMA PRAC</p>	<p style="text-align: right;">Page 160</p> <p>1 A So we say that they concluded that the</p> <p>2 evidence didn't support -- which is in their</p> <p>3 conclusions -- but then we say, "yet doubts and</p> <p>4 concerns persist."</p> <p>5 Q Okay.</p> <p>6 A And then we cite the work of Rebecca</p> <p>7 Chandler and Tom Jefferson.</p> <p>8 And I agree that doubts and concerns</p> <p>9 persist, so I am in agreement here, not with EMA --</p> <p>10 and that's -- this is the -- I'm in agreement with</p> <p>11 Rebecca Chandler and Tom Jefferson, that there were</p> <p>12 still doubts persisting.</p> <p>13 And I will give you a very -- example of</p> <p>14 it here. When they discussed the work by Rebecca</p> <p>15 Chandler and the Uppsala Monitoring Centre, which</p> <p>16 should be somewhere here in --</p> <p>17 Q Okay. Let --</p> <p>18 A -- this report --</p> <p>19 Q Hold on.</p> <p>20 Let me -- let me --</p> <p>21 A -- it says on page --</p> <p>22 Q We got to --</p> <p>23 A -- twenty-six --</p> <p>24 Q Okay. We got to --</p> <p>25 A -- and 27, it discusses the report.</p>
<p style="text-align: right;">Page 159</p> <p>1 assessment report a detailed scientific review;</p> <p>2 correct?</p> <p>3 MR. BAUM: Objection. Vague.</p> <p>4 BY MR. TOMASELLI:</p> <p>5 Q I'm just reading your words, Doctor.</p> <p>6 A That's what I wrote in the paper,</p> <p>7 "detailed scientific review."</p> <p>8 Q Okay. And you also wrote in the paper</p> <p>9 that that EMA assessment report did not support a</p> <p>10 causal link between HPV vaccines and CRPS or POTS;</p> <p>11 correct?</p> <p>12 A I wrote that "they concluded." So the</p> <p>13 EMA concluded that the evidence did not support or</p> <p>14 cast a link between HPV vaccines and CRPS and POTS.</p> <p>15 That is what -- that's correct, they did not</p> <p>16 conclude that.</p> <p>17 Q The EMA concluded that?</p> <p>18 A They -- the EMA did not concluded that --</p> <p>19 so I wrote what the EMA concluded.</p> <p>20 Q That's right.</p> <p>21 A And I also -- and then we wrote, and this</p> <p>22 is both me and my coauthors, "yet doubts and</p> <p>23 concerns persists." And we referenced the papers by</p> <p>24 Rebecca Chandler and Tom Jefferson.</p> <p>25 Q Right.</p>	<p style="text-align: right;">Page 161</p> <p>1 And it says, "The second analysis" -- and</p> <p>2 this here they are doing a disproportionality</p> <p>3 analysis.</p> <p>4 It says, "The second analysis compare</p> <p>5 45,876 worldwide HPV vaccine reports against 79,678</p> <p>6 worldwide reports for all other vaccines combined</p> <p>7 and received for females between the age of nine and</p> <p>8 25."</p> <p>9 If you then go down -- this is page 27.</p> <p>10 If you go down to the second last</p> <p>11 paragraph on this page, it says "POTS has been</p> <p>12 reported 82 times for HPV vaccine and one time for</p> <p>13 other vaccines."</p> <p>14 So that is 82 times out of 45,000, versus</p> <p>15 one time out of 79,000. So this is a -- a huge</p> <p>16 concern. These are a disproportionality of more</p> <p>17 than a hundred.</p> <p>18 And then what they do is they say, Well,</p> <p>19 this is 0.2 percent versus 0.0 percent. That sounds</p> <p>20 almost the same.</p> <p>21 Q Not to me.</p> <p>22 A 0.2 or 0.0, but this is actually a huge</p> <p>23 difference in the reporting ratios.</p> <p>24 Q Okay. So let's --</p> <p>25 A So this is --</p>

<p style="text-align: right;">Page 162</p> <p>1 Q We need to go question and answer here. 2 So let me -- believe me, I'll give you a chance to 3 talk about that, okay? 4 A Okay. Thank you. 5 Q Okay. So I think what you are saying is 6 that you've read the EMA's November 2015 assessment 7 report related to whether HPV vaccines are 8 associated with POTS; correct? 9 A I read that report, yes. 10 Q And part of that report -- 11 A Most of it. 12 Q Part of that report discusses a 13 disproportionality analyses that the Uppsala 14 Monitoring senator [sic] for WHO performed for the 15 Danish Health Authority; correct? 16 A They performed it. I don't know if they 17 performed it for the Danish Health Authority or for 18 someone else. 19 Q Okay. 20 A They do these things on their own for 21 a -- 22 Q Okay. 23 A -- so I don't know who they performed it 24 for. 25 Q And regardless, the EMA had this</p>	<p style="text-align: right;">Page 164</p> <p>1 2015, in connection with the Article 20, there was 2 already a report related to disproportionality of 3 POTS and POTS-like symptoms that was available for 4 people to review; true? 5 A That is very true. 6 Q Okay. And then all you are saying in Yih 7 2018, is that while -- withdrawn. 8 In Yih 2018, you quoted the EMA, is that 9 they concluded based on their analysis of the data 10 that there was -- that the evidence did not support 11 a causal link between HPV vaccines and POTS; right? 12 That's what they said? 13 A That's what EMA said. 14 Q And you go on to say that there are some 15 other papers and other authors that continue with 16 concerns after that report; fair? 17 A Correct. 18 Q Okay. One of those -- see, we have to do 19 this question and answer. I'm trying to let you 20 answer but we got to do it -- we can't ramble on 21 for -- for hours and hours or our court reporter is 22 going to kill us. Okay? 23 So withdrawn. 24 (Whereupon, Exhibit MK 22, Rebecca 25 Chandler Paper, was marked for</p>
<p style="text-align: right;">Page 163</p> <p>1 disproportionality analysis that was done in 2 connection with the Article 20 procedure in 2015; 3 right? 4 A What did you ask? 5 Q The EMA and the PRAC members and 6 everybody associated with the Article 20 procedure 7 had this disproportionality analysis during the 8 procedure; right? 9 A Yes. They are citing it so they must 10 have had it. 11 Q Okay. And so the -- the PRAC members, 12 the rapporteurs, the corapporteurs, the EMA itself, 13 the Scientific Advisory Group, they all had access 14 to that disproportionality analysis related to POTS 15 and POTS-like symptoms; right? 16 A Whoever wrote this report had it. I 17 don't know exactly who wrote this report, if they 18 are all those people that you mentioned or not. 19 Q Well, all those people were provided the 20 report -- 21 A Okay. 22 Q -- and so they must have had access to 23 it. 24 A Okay. Good. 25 Q Okay. And -- and so there was already in</p>	<p style="text-align: right;">Page 165</p> <p>1 identification.) 2 BY MR. TOMASELLI: 3 Q One of the reports that you cited there 4 was Exhibit 22, which I've marked, Chandler 2017. 5 Do you see that? 6 A Yes. 7 Q And that is indeed the paper you cited in 8 Yih 2018 as continuing potential concerns over HPV 9 vaccination and POTS-like symptoms; right? 10 A That was one of three papers that we 11 cited on that. 12 Q Okay. Well, the other paper is a like 13 a -- a letter to the editor, an opinion piece by 14 Chandler; right? 15 A There is one other piece by Chandler and 16 then there's one by Tom Jefferson -- 17 Q Right. 18 A -- which... 19 Q And to be clear, the Tom Jefferson paper 20 is a review, it's not original data; right? 21 A I will have to look up the -- the exact 22 papers to -- to refresh. I haven't read them in 23 quite some time. 24 Q Okay. At least one of the papers is 25 Exhibit 22 that I've handed you which is Chandler</p>

<p style="text-align: right;">Page 166</p> <p>1 2017; right?</p> <p>2 A Yes.</p> <p>3 Q You can confirm that Chandler 2017 is a 4 particular type of disproportionality analysis that 5 is a proportional reporting ratio; right?</p> <p>6 A Yes. They use proportional reporting 7 ratios.</p> <p>8 Q And like other proportional reporting 9 ratios and disproportionality analysis, this was a 10 signal generation paper; correct?</p> <p>11 A You'll have to ask Dr. Chandler and her 12 colleagues.</p> <p>13 Q Did you read this paper?</p> <p>14 A I have read it.</p> <p>15 Q Okay. If you -- do you -- do you agree 16 that based on this "paper" -- based on this paper, a 17 causal association between HPV vaccination and these 18 adverse event symptoms remains uncertain?</p> <p>19 A I agree with the conclusion made by 20 Dr. Chandler and her colleagues where she writes on 21 page 89, using this particular paper, "A causal 22 association between these AEs and HPV vaccination 23 remain uncertain" --</p> <p>24 (Whereupon, the court reporter 25 requests clarification.)</p>	<p style="text-align: right;">Page 168</p> <p>1 that was done, I think, by Rebecca Chandler who 2 works at the Uppsala Monitoring Centre.</p> <p>3 Q Okay.</p> <p>4 A But this was a specific thing that they 5 did a specific classed analysis. So they had done 6 disproportionality analysis before this paper, 7 actually.</p> <p>8 Q Right. And so my simple point, maybe 9 very inarticulately put forth to you, but -- 10 withdrawn.</p> <p>11 My simple point is simply that there are 12 two different disproportionality analyses that we 13 are talking about, one that was done in connection 14 with the 2015 Article 20, and one that was published 15 in Chandler 2017.</p> <p>16 Correct?</p> <p>17 A Yeah. So they were not -- there were two 18 different analysis that they did.</p> <p>19 Q Right. But they both dealt with POTS and 20 POTS-like symptoms; correct?</p> <p>21 A I believe so, yes.</p> <p>22 Q Okay.</p> <p>23 (Whereupon, Exhibit MK 23, European 24 Medicines Agency PRAC PSUR Assessment 25 Report, dated January 2017, was</p>
<p style="text-align: right;">Page 167</p> <p>1 A -- "these AEs" -- A-E-s -- "and HPV 2 vaccination remain uncertain; however, given the 3 medical seriousness of this safety concern, we 4 believe that a more definitive study of the findings 5 presented here is essential to assure continued 6 confidence in the HPV vaccine."</p> <p>7 So I agree with their assessment.</p> <p>8 Q Okay. So you also agree with the part of 9 their assessment that a causal association remains 10 uncertain?</p> <p>11 A Based on this -- on this particular 12 paper.</p> <p>13 Q Right. Have you ever reviewed the EMA's 14 analysis of the Chandler paper?</p> <p>15 A They -- you mean different from what they 16 wrote in their -- in their report that you -- that 17 was Exhibit 21?</p> <p>18 Q Well, Exhibit 21, the assessment report, 19 deals with a disproportionality analysis from the 20 WHO Uppsala spontaneous database. The Chandler 21 publication is actually slightly different.</p> <p>22 Did you know that?</p> <p>23 A I know they are not identical because 24 this does a classed analysis so this is a specific 25 thing. They did other disproportionality analysis</p>	<p style="text-align: right;">Page 169</p> <p>1 marked for identification.)</p> <p>2 BY MR. TOMASELLI:</p> <p>3 Q Exhibit 23 is a document dated 4 January 2017 from the European Medicines Agency 5 called PRAC, PSUR assessment report.</p> <p>6 Do you see that?</p> <p>7 A Yes.</p> <p>8 Q Have you ever seen this before?</p> <p>9 A I don't think I've read this one, no.</p> <p>10 Q Okay. If you turn to page 16 of 29 -- 11 tell me when you are there?</p> <p>12 A Yeah.</p> <p>13 Q Do you see there's a box with -- language 14 in a box?</p> <p>15 A Yeah.</p> <p>16 Q And are you familiar with that there are 17 rapporteur's within the EMA and PRAC that go through 18 various data and give their thoughts about it?</p> <p>19 A I'm not -- I'm much more familiar with 20 the FDA system than the EMA system --</p> <p>21 Q Okay.</p> <p>22 A -- so I -- I -- I'm certainly not an 23 expert on the EMA system --</p> <p>24 Q And --</p> <p>25 A -- and those things.</p>

<p style="text-align: right;">Page 170</p> <p>1 Q Okay. That -- that was part of actually 2 what I was going to ask you, is whether you are 3 familiar that -- with the fact that there is the 4 EMA, and how the PRAC is associated with the EMA, and how 5 and how the CHMP is associated with the EMA, and how 6 rapporteurs are associated with the EMA, and how the 7 Scientific Advisory Group is -- is affiliated with 8 the EMA; that's not something you are familiar with?</p> <p>9 A That's not my area of expertise.</p> <p>10 Q Okay. If we read the first paragraph of 11 this box, it says, "Rapporteur assessment comment: 12 Both of these papers were identified and assessed as 13 late-breaking information by the Gardasil Rapporteur 14 in the PSUSA for Gardasil, which is running 15 concurrently with the procedure for Gardasil 9."</p> <p>16 Do you see where I am?</p> <p>17 A Yes.</p> <p>18 Q Then says, "Although the analysis of 19 VigiBase in this paper by Chandler, et al., was 20 different to the analysis from the Uppsala 21 Monitoring Centre that was considered in the Article 22 20 referral in 2015..."</p> <p>23 Do you see where I am?</p> <p>24 A Yup.</p> <p>25 Q And it's true that Chandler did use the</p>	<p style="text-align: right;">Page 172</p> <p>1 today, you do see on the first page that there's an 2 abstract of the paper; right?</p> <p>3 A Meaning of the -- of the -- of the Yih 4 2018 paper?</p> <p>5 Q Yes.</p> <p>6 A Yes, I see that there.</p> <p>7 Q And abstracts are short summaries of the 8 key points of the article?</p> <p>9 A That's one purpose of them, yes.</p> <p>10 Q Okay. At least to give the author -- I'm 11 sorry. Withdrawn.</p> <p>12 The purpose of an abstract is at least to 13 give the reader a flavor for what the paper is 14 about?</p> <p>15 A Yeah. And that way they can get some 16 information from it and they can decide whether they 17 want to read the full paper or not.</p> <p>18 Q Okay.</p> <p>19 A So it's very helpful to have those 20 abstracts.</p> <p>21 Q And the conclusion of the abstract, the 22 last sentence, says, "Considering the thousands of 23 potential short term adverse events and hundreds of 24 potential risk intervals were evaluated, these 25 findings add significantly to the growing safety</p>
<p style="text-align: right;">Page 171</p> <p>1 VigiBase spontaneous database for her analysis; 2 right?</p> <p>3 A I think so for both papers, I believe.</p> <p>4 Q Yeah. It says, "Although the VigiBase 5 data from Chandler was different from the article 20 6 database analysis, the same general limitations 7 apply."</p> <p>8 Do you see that?</p> <p>9 A Yes, I see that.</p> <p>10 Q And it says, "Data-mining these 11 non-specific symptoms does not strengthen the safety 12 signal nor does it inform the causality assessment. 13 We therefore agree with the Gardasil Rapporteur's 14 assessment, i.e. that the previous PRAC conclusion 15 that there was no evidence that the HPV vaccines 16 caused POTS or CRPS remains unchanged and that this 17 publication," Chandler, "does not result in any new 18 safety concerns regarding Gardasil 9."</p> <p>19 Do you see that?</p> <p>20 A I see that.</p> <p>21 Q Okay. And you've never seen this 22 document before; right?</p> <p>23 A I don't think so.</p> <p>24 Q Okay. In terms of Yih 2018, if we go 25 back to that publication we have been talking about</p>	<p style="text-align: right;">Page 173</p> <p>1 record of Gardasil."</p> <p>2 A Yes.</p> <p>3 Q Do you see that?</p> <p>4 A Yeah.</p> <p>5 Q And you agree with that?</p> <p>6 A Yeah. I'm very proud of having done 7 the -- help out with this paper.</p> <p>8 Q It is true that in the 2018 Yih paper, 9 you never suggested that there was a safety concern 10 with Gardasil; correct?</p> <p>11 A We do say, "yet doubts and concerns 12 persist." We mention that --</p> <p>13 Q You --</p> <p>14 A -- for particular -- for particular -- 15 these things between CRPS and POTS.</p> <p>16 Q You never -- will you agree -- withdrawn.</p> <p>17 Dr. Kulldorff, would you agree that in 18 your paper, Yih 2018, you provided no evidence from 19 a data perspective that Gardasil was associated with 20 the development of POTS?</p> <p>21 A Correct.</p> <p>22 Q Okay. Would you also agree that that is 23 true for POI and fibromyalgia and chronic fatigue 24 syndrome?</p> <p>25 A That is true that this paper does not</p>

<p style="text-align: right;">Page 174</p> <p>1 include any evidence that Gardasil causes any of 2 these things, neither does it necessarily contradict 3 it. Certainly not for CRPS and POTS, as explained 4 here by me and my coauthors.</p> <p>5 Q Right. And I'm not saying one way or the 6 other -- withdrawn.</p> <p>7 We can agree your Yih 2018 paper does not 8 provide any evidence for an increased risk of POTS 9 or POI for Gardasil; correct?</p> <p>10 A That is true.</p> <p>11 Q Okay. Now Yih 2018, Exhibit 7 that we've 12 been talking about, deals with Gardasil 4; correct?</p> <p>13 A It does.</p> <p>14 There's a subsequent paper on GARDASIL®9, 15 actually, that uses a similar methodology.</p> <p>16 Q We are on the same page, Doctor.</p> <p>17 A I guess you have that as an exhibit.</p> <p>18 (Whereupon, Exhibit MK 24, Paper by 19 Yih, 2021, American Journal of 20 Epidemiology, was marked for 21 identification.)</p> <p>22 BY MR. TOMASELLI:</p> <p>23 Q Doctor, I've marked as Exhibit 24, a 24 paper by Yih from 2021, that was published in the 25 American Journal of Epidemiology; correct?</p>	<p style="text-align: right;">Page 176</p> <p>1 certain health outcomes and not found any 2 associations"?</p> <p>3 Do you see that?</p> <p>4 A Correct.</p> <p>5 Q And you actually go on to cite six 6 different publications with respect to that 7 statement; right?</p> <p>8 A Yes.</p> <p>9 Q And they are the Scheller paper, the 10 Naleway paper, the Yih 2016 paper, the 11 Grimaldi-Bensouda 2017 paper, the Feiring paper, and 12 the Miranda paper; correct?</p> <p>13 A Correct.</p> <p>14 Q And again, you used the self-controlled 15 temporal TreeScan method here; correct?</p> <p>16 A I -- I believe so, yes. Let me make sure 17 that --</p> <p>18 Q Sure?</p> <p>19 A -- just --</p> <p>20 Yes.</p> <p>21 Q Here again, you scanned for tens of 22 thousands of issues and multiple different time 23 frames; right?</p> <p>24 A Many issues and many time frames.</p> <p>25 Q And the time frames even went up to one</p>
<p style="text-align: right;">Page 175</p> <p>1 A Yes, it was.</p> <p>2 Q You are a coauthor; right?</p> <p>3 A Yes.</p> <p>4 Q Again, all of your authors are interested 5 in public safety and health; correct?</p> <p>6 A These are my three coauthors, are 7 excellent sci- -- excellent people. Two of them 8 are -- are scientists, excellent scientists.</p> <p>9 Q Partly because you trained them; right?</p> <p>10 A Well, I'll refrain from responding to 11 that question.</p> <p>12 Q Well, Dr. Kulldorff, Dr. Yih and 13 Dr. Maro, you certainly mentored them; right?</p> <p>14 A Yes.</p> <p>15 Q They are excellent physician -- I mean, 16 they are excellent -- withdrawn.</p> <p>17 Both Dr. Yih and Dr. Maro are excellent 18 scientists; correct?</p> <p>19 A Yes.</p> <p>20 And Inna Deshevsky is an excellent person 21 but she's not a scientist.</p> <p>22 Q Now, at the bottom of page one of Yih 23 2021, which is Exhibit 24, do you see where you say, 24 "A number of well-designed studies have investigated 25 possible associations between HPV vaccination and</p>	<p style="text-align: right;">Page 177</p> <p>1 year out; correct?</p> <p>2 A Yeah. So the previous paper I think we 3 looked eight weeks -- up to eight weeks. Here we 4 looked further. I think -- what is it, a year or 5 so?</p> <p>6 Q I think you can read in the abstract, if 7 it helps you?</p> <p>8 A Yeah, to one year.</p> <p>9 Q And why is it you went up to a year for 10 the time period of the window of latency that you're 11 looking at?</p> <p>12 A To extend the -- the analysis.</p> <p>13 So when you look at vaccine safety, 14 whatever you do, there are certain limitation what 15 you are looking at. It could be based on the 16 outcomes or based on when things happened.</p> <p>17 So we wanted to look for adverse event 18 that doesn't only happen very soon, within a few 19 weeks after the vaccine, but also be able to detect 20 things -- if they happened several months after 21 vaccination. So we wanted to sort of extend the net 22 or the coverage that we are doing in this paper.</p> <p>23 Q And like your 2018 paper, is this 24 TreeScan paper a method of generating a signal, 25 potentially, if there's an issue?</p>

<p style="text-align: right;">Page 178</p> <p>1 A It's a data-mining methods, so it's used 2 for a signal -- to -- to find out if there's a 3 signal somewhere, yeah.</p> <p>4 Q Do you -- do you believe that these 5 hierarchical TreeScan methods of generating a signal 6 are more in depth than, for example, a case report? 7 a single case report?</p> <p>8 A Yes.</p> <p>9 Q Would you say the same thing about a 10 series of patients, a case series? Instead of one 11 individual, several individuals?</p> <p>12 A Well, that depends. So I can't say 13 anything conclusive one way or the other there.</p> <p>14 Q Do you think your TreeScan method is more 15 capable of generating a hypothesis about a vaccine 16 safety issue than a case series?</p> <p>17 A No, they compliment each other.</p> <p>18 So I think both are very valid for doing 19 those things. I mean, the case here is just a more 20 old-time established way of doing things. So this 21 is sort of a additional -- a -- complementary to do 22 it in a different way that sometimes can detect 23 things that would not be detected by a case series.</p> <p>24 Q A case series -- withdrawn.</p> <p>25 Case series have been published in the</p>	<p style="text-align: right;">Page 180</p> <p>1 scope of the evaluation and the high statistical 2 power, the findings of no specific serious adverse 3 events should provide reassurance about this 4 vaccine's safety."</p> <p>5 Do you see that, sir?</p> <p>6 A Yes, I see that.</p> <p>7 Q And you agreed with that when it was 8 published in 2021; correct?</p> <p>9 A I did, yes.</p> <p>10 Q And would you also agree that this Yih 11 2021 paper did not provide any evidence for the fact 12 that Gardasil is associated with an increased risk 13 of POTS?</p> <p>14 A That is true. When we wrote this thing 15 about that, "provide reassurance about this 16 vaccine's safety," I think that is very true because 17 we looked at so many things that nobody else had 18 looked at.</p> <p>19 At the same time, in the discussion, me 20 and my coauthor, we write that "We might have missed 21 true adverse reactions if they did not show strong 22 clustering in time or in the diagnosis tree."</p> <p>23 This is page 1258, left column, second 24 paragraph from the left -- from the bottom.</p> <p>25 "Not all plausible vaccine-associated</p>
<p style="text-align: right;">Page 179</p> <p>1 literature over a very long time about whether an 2 intervention is related to an event; right?</p> <p>3 A Well, you -- you can report you had five 4 people, they all had this drug or vaccine and they 5 all experienced this outcome.</p> <p>6 Q I thought I understood you to say that 7 that was a long-standing way of raising a 8 hypothesis?</p> <p>9 A It is. Yes.</p> <p>10 Q Okay. And in terms of raising a 11 hypothesis about adverse events, your tree-scanning 12 method that looks at a number of adverse events over 13 a number of windows is a more sophisticated way of 14 looking for those signals?</p> <p>15 A From a methodological point of view it's 16 a more sophisticated way, yes.</p> <p>17 Q Okay. Otherwise we wouldn't have a job; 18 right?</p> <p>19 I mean --</p> <p>20 A No, yeah. I --</p> <p>21 Q -- your methods are -- your methods are 22 worth something; right?</p> <p>23 A I hope so.</p> <p>24 Q Now, in your abstract of the 2021 paper, 25 the very last sentence says, "Considering the broad</p>	<p style="text-align: right;">Page 181</p> <p>1 syndromes affect just one system of the body. For 2 instance, postural orthostatic tachycardia syndrome 3 (POTS) is a heterogenous and potentially delib- -- 4 debilitating autonomic disorder whose symptoms can 5 include dizziness, nausea, fatigue, palpitations, 6 weakness, sweating, and sleeping disorder.</p> <p>7 "A case series of POTS occurring after 8 HPV4 vaccination in Denmark raised concern about a 9 possible association.</p> <p>10 "Although there is an ICD-10 code for 11 orthostatic hypotension (I95.1), some POTS cases 12 might be coded as neurological, gastrointestinal, or 13 other kinds of conditions and thus be less 14 detectable as a cluster in the ICD-10 diagnosis 15 tree."</p> <p>16 So again, this refers to the thing that 17 if you use these ICD-10 codes that we used, as well 18 as others had used in Denmark and -- and Finland and 19 so on, there's a weakness there of finding, in 20 particular, POTS and other ill-defined or -- or more 21 broadly-defined syndromes.</p> <p>22 So we sort of pointed that out in this 23 paper, that even though we cast a net very widely, 24 and that provide additional assurance that it 25 doesn't cause X or Y that nobody had thought about</p>

<p style="text-align: right;">Page 182</p> <p>1 before, we would not expect this method to have the 2 ability to detect a problem in POTS because it 3 doesn't fit in with these ICD codes. 4 Q Well, you say -- well, first of all -- 5 withdrawn. 6 In terms of the case series that you 7 mention here about raising concern, that's the 8 Brinth and Melson case series from Denmark; correct? 9 A Let me just check this number 22. 10 Brinth, yes. 11 Q And you can confirm that since you've 12 read it in detail, the EMA's assessment report from 13 2015 also considers the Brinth and Melson case 14 series; correct? 15 A So when we talked about it before, we 16 talked about the Uppsala Monitoring Centre, which -- 17 Q That's right. 18 A -- is different from the Brinth. But I 19 think they also -- they also considered the Brinth 20 work, yes. 21 Q Yeah. In the 42 -- 22 A Yes. 23 Q -- pages -- 24 A -- they -- 25 Q -- they did --</p>	<p style="text-align: right;">Page 184</p> <p>1 Q -- true? 2 A Yes. 3 Q And the same is true for POI and -- and 4 fibromyalgia; correct? 5 A Correct. 6 Q Now, again, in this 2021 paper, you did 7 not suggest that there was a serious safety concern 8 with respect to POTS, you just noted that it was a 9 limitation of the paper; correct? 10 A We noticed that there has been concern 11 about these things and that, as a limitation not 12 just of the paper but other methods, we do not 13 expect to pick it up because of the -- the -- the 14 wide variety of how this syndrome is defined. 15 Q And did you follow up with that concern 16 in doing any other research yourself with Dr. Yih or 17 Dr. Maro in whether Gardasil caused POTS? 18 A No. 19 Q Okay. Let's talk a little more about the 20 Article 20 procedure that you discussed in your 21 expert report; okay? 22 A That sounds good. 23 Q You do not dispute, of course, that the 24 EMA and the Pharmacovigilance Risk Assessment 25 Committee, the PRAC, you don't dispute that they are</p>
<p style="text-align: right;">Page 183</p> <p>1 A -- they mentioned that also. We haven't 2 discussed that before, but they do mention that, 3 yes. 4 Q Okay. And again, Brinth's case series is 5 the same thing as -- as -- that -- that Dr. Melson. 6 They were together in that -- in that center in -- 7 in Denmark; are you aware of that? 8 A I think they were looking at the same 9 things but I have read -- 10 (Whereupon, there was an 11 interruption.) 12 A I have looked at both of them and I think 13 they are the same, but I can't say that under oath. 14 BY MR. TOMASELLI: 15 Q Do you need to get that? 16 A (The witness shakes head.) 17 Q You -- you say in this paper, and you 18 read to me, that -- that these conditions, like CRPS 19 and POTS, would be less detectable than -- than 20 others, not not detectable; right? 21 A Yes. 22 Q So again, this paper, Yih 2021, does not 23 provide any evidence for the fact that Gardasil is 24 associated with an increased risk of POTS -- 25 A Correct.</p>	<p style="text-align: right;">Page 185</p> <p>1 experts in public safety and -- and have the safety 2 of the public in the forefront of their mind, do 3 you? 4 A I have actually no idea who they are. I 5 don't know the names of them. 6 Q Okay. You don't -- 7 A So I -- I don't want to preview -- to 8 have any opinion on that because I don't know who 9 they are. 10 It may be public, their names, but I 11 don't think I have seen it. Or if I have seen it, I 12 don't remember it. 13 THE WITNESS: It is 12:45 now. 14 MR. BAUM: It is? 15 THE WITNESS: If you want to finish 16 something, we can do that, probably. 17 MR. TOMASELLI: Yeah. Let's -- 18 let's just do two minutes. 19 THE WITNESS: Okay. Good. 20 MR. TOMASELLI: And then -- I 21 just -- 22 THE WITNESS: Okay. 23 MR. TOMASELLI: -- want to clear one 24 thing up -- 25 THE WITNESS: Perfect.</p>

<p style="text-align: right;">Page 186</p> <p>1 MR. TOMASELLI: -- that you didn't 2 know or didn't -- 3 THE WITNESS: Okay. 4 MR. TOMASELLI: Withdrawn. 5 (Whereupon, Exhibit MK 25, Report 6 From Danish Health and Medicines 7 Authority for Consideration by the 8 EMA and Rapporteurs, was marked for 9 identification.) 10 BY MR. TOMASELLI: 11 Q I'm handing you what I've marked as 12 Exhibit 25, which is a -- sorry -- which is a 13 "Report from the Danish Health and Medicines 14 Authority for consideration by the EMA and 15 rapporteurs..." 16 Do you see that? 17 A Yes. 18 Q And do you see that it's dated April of 19 2015? 20 A Yes. 21 Q Okay. And if you can confirm on page 19 22 that there is a, you know, 20-page appendix or so 23 that relates to information from the Uppsala 24 Monitoring senator [sic] regarding spontaneous cases 25 in the VigiBase database; right?</p>	<p style="text-align: right;">Page 188</p> <p>1 (Whereupon, there was a recess taken 2 from 12:46 p.m. to 1:37 p.m.) 3 THE VIDEOGRAPHER: The time is 4 1:37 p.m. and we are on the record. 5 BY MR. TOMASELLI: 6 Q All right. Dr. Kulldorff, are you 7 prepared to continue with your deposition? 8 A Yes. 9 Q Great. 10 Exhibit 21, which is right on the top 11 there, is the EMA assessment report from November 12 '15; right? 13 A Yes. 14 Q And you reviewed this; right? 15 A Yes. 16 Q If you turn to the third page, do you see 17 there's a section on background information? 18 A Uh-huh. 19 Q And going to the, actually, the last 20 paragraph and working back up, the very last 21 paragraph says on July 9, 2015, the European 22 Commission triggered a procedure under Article 20 23 for this; right? 24 A Yup. 25 Q So the Article 20 procedure was initiated</p>
<p style="text-align: right;">Page 187</p> <p>1 A Page 19? 2 Q Eighteen. Sorry. 3 A Okay. Appendix two. 4 Okay. Yes. 5 Q Yeah. So does this -- again, I think you 6 were questioning whether the Danish health and -- 7 the Danish Health and Medicine's Authority 8 commissioned the Uppsala Monitoring senator -- 9 Center's disproportionality analyses. And I was 10 just trying to show you that, indeed, that's -- 11 that's who did it. 12 A Okay. Yeah, I -- I wasn't aware of who 13 commissioned it or who, so... 14 Q Okay. But in -- in any event, if this 15 was provided in April of 2015, would you agree that 16 the EMA obviously had this analysis before they put 17 it into their assessment report? Fair? 18 A That makes sense, yes. 19 Q Okay. 20 MR. TOMASELLI: Why don't we go 21 ahead and take your -- your lunch 22 break. 23 THE WITNESS: Okay. 24 THE VIDEOGRAPHER: The time is 25 12:46 p.m. and we are off the record.</p>	<p style="text-align: right;">Page 189</p> <p>1 in -- in July of -- of 2015; right? 2 A Correct. 3 Q And if we go up a few paragraphs, do you 4 see a paragraph that starts, "Routine 5 surveillance"? 6 A Yes. 7 Q Three lines down, very end, there's a 8 sentence that starts -- or sorry, the fourth -- 9 four lines down, there's a sentence that starts -- 10 withdrawn. 11 Four lines down there's a sentence that 12 starts, "These syndromes have been reviewed 13 repeatedly since 2013 by the PRAC within routine 14 safety follow-up measures [sic] and a relationship 15 with HPV vaccines has not been concluded in these 16 previous procedures." 17 Do you see that? 18 A Yes. 19 Q Did you know that the EMA and PRAC had 20 been looking at this issue for a couple years before 21 then? 22 A No. But I assume that EMA, just like the 23 FDA, would consider all types of adverse events 24 because this -- they have to do that, basically, for 25 every product --</p>

<p style="text-align: right;">Page 190</p> <p>1 Q You had -- 2 A -- in some way or another. 3 Q Fair enough. 4 But you didn't know that they were 5 particularly focused in on -- 6 A No. 7 Q -- POTS for the -- for two years prior to 8 the Article 20? 9 A No. 10 Q Okay. And I take it from that you did 11 not review, for example, all of the back and forth 12 between Merck and the EMA and PRAC in the two years 13 prior to the Article 20? 14 A I only reviewed the Merck response to the 15 Article 20 that was provided to me. Yes. 16 Q Fair enough. 17 And in the very next paragraph or, sorry, 18 two paragraphs later, it says "These syndromes" -- 19 that is POTS and CRPS -- "have been known for a long 20 time before the introduction of the HPV vaccines." 21 Do you see that? 22 A I see that. 23 Q And we talked about that earlier; right? 24 A Yes, we did. 25 Q Okay. Your report -- actually, one other</p>	<p style="text-align: right;">Page 192</p> <p>1 but you were aware of it, because we talked about it 2 earlier, that, you know, you knew -- 3 A I have read this. 4 Q Fair enough. 5 And in terms of your written report in 6 this litigation, it's true that your report contains 7 no analysis or opinions related to the EMA's 8 conclusions; correct? Related to the Article 20? 9 A Well, what they wrote here is related to 10 the Merck report. And so in that sense, my -- my 11 comments on the Merck report is, therefore, at least 12 indirectly also related to this because it's on the 13 same topic. 14 Q Okay. 15 A But I didn't really -- I didn't respond 16 or try to respond to specific things in this report. 17 That was not my task. 18 Q Perfect. 19 And same question: Your report -- expert 20 report in this case doesn't contain any opinions 21 regarding what the Scientific Advisory Group said or 22 any of the rapporteurs or corapporteurs said about 23 these issues related to HPV vaccination and POTS; 24 correct? 25 A Correct.</p>
<p style="text-align: right;">Page 191</p> <p>1 thing while we are in this document, will you turn 2 over to page seven, please? 3 Do you see there's a box? 4 A Yes. 5 Q Okay. The paragraph below that box, 6 there is a sentence that starts about five lines 7 down that says, "It is estimated." 8 Do you see that sir? 9 A Yes. 10 Q It says, "It is estimated that at least 11 150 girls and young women per million may develop 12 POTS each year." 13 Do you see that? 14 A Yes, I see that. 15 Q And that was part of your review when you 16 reviewed this report; correct? This assessment 17 report? 18 A Yes. I -- well, I didn't review this 19 report. I reviewed the report that Merck sent to 20 EMA. 21 Q Okay. Well -- 22 A This is the -- this report is what the 23 EMA wrote. I had -- I didn't review this for the -- 24 my report. 25 Q Not for your expert report in this case</p>	<p style="text-align: right;">Page 193</p> <p>1 My report was just about what Merck sent 2 to the EMA, and also, I guess, the questions that -- 3 based on the questions that EMA had sent to Merck. 4 (Whereupon, Exhibit MK 26, Merck 5 Report Reviewed in Connection with 6 the Article 20 Procedure, was marked 7 for identification.) 8 BY MR. TOMASELLI: 9 Q And in terms of that Merck report that 10 you discussed and that you reviewed, is Exhibit 26 11 the Merck report that you reviewed in connection 12 with the Article 20 procedure? 13 A Yes. 14 Q And we can agree that very specific 15 questions were asked of Merck by the EMA in regards 16 to that procedure; correct? 17 A Yes. 18 Q And in terms of one of the questions they 19 asked was to review the clinical trial database for 20 cases of POTS; right? 21 A Yes. 22 Q You remember that; yes? 23 A Yes. 24 Q And in fact, you would agree that Merck 25 did a careful review of the POTS cases that occurred</p>

<p style="text-align: right;">Page 194</p> <p>1 as part of the clinical trials; right?</p> <p>2 MR. BAUM: Objection.</p> <p>3 Mischaracterizes what his report says.</p> <p>4 BY MR. TOMASELLI:</p> <p>5 Q Dr. Kullendorff, just so you have -- my 6 question is you would agree that Merck did a careful 7 review of the CRPS and POTS cases that occurred as 8 part of the clinical trials?</p> <p>9 MR. BAUM: And I object to the 10 degree that it calls for him to know what 11 was in Merck's minds relative to whether 12 or not they were careful.</p> <p>13 BY MR. TOMASELLI:</p> <p>14 Q You can answer.</p> <p>15 MR. BAUM: Calls for speculation.</p> <p>16 A Are you citing anything from my report?</p> <p>17 BY MR. TOMASELLI:</p> <p>18 Q Do you agree?</p> <p>19 A So they did review all the individual 20 cases and I have no complaints about the way they 21 did that. I do have a complaints about how they 22 interpret some of that.</p> <p>23 For example, it was incorrect, I think 24 of -- of -- to write in the MAH that the incidence 25 of cases suggestive of POTS was found to be</p>	<p style="text-align: right;">Page 196</p> <p>1 MR. BAUM: Objection. Calls for 2 speculation.</p> <p>3 BY MR. TOMASELLI:</p> <p>4 Q Yes? No?</p> <p>5 THE WITNESS: Should I answer or 6 not?</p> <p>7 BY MR. TOMASELLI:</p> <p>8 Q Yes, you can answer.</p> <p>9 A Okay. So they looked at everybody who 10 had POTS in the clinical trials and they carefully 11 looked at the -- at the records for those people. 12 So that, I think, they -- that was done properly.</p> <p>13 What was not done properly was when they 14 made conclusions and saying that the incidence of 15 these cases suggestive of POTS was found to be 16 extremely lower, or when it said that the incidence 17 was similar between the 9vHPV and placebo groups, or 18 it was also, I think, misleading to state that this 19 assessment does not suggest an association between 20 HPV vaccination and POTS.</p> <p>21 There wasn't proof of such association 22 because the sample size was very small. But one 23 thing that clinical -- I mean, if you see in a -- in 24 a clinical trial, if you see a big effect --</p> <p>25 Q So this is -- my question was very</p>
<p style="text-align: right;">Page 195</p> <p>1 extremely low. I think that is incorrect.</p> <p>2 Q Why is --</p> <p>3 A It's also --</p> <p>4 Q -- that?</p> <p>5 A Because incidence is not a total number 6 of cases, it's the proportion -- it's the number of 7 cases divided by the number of people exposed. So 8 if you have a clinical trial which, let's say a 9 thousand people, even if you have two cases, that is 10 one out of 50 as the point estimate. That's not a 11 low number of a serious adverse reaction.</p> <p>12 On the other hand, if you have two, that 13 could be maybe by chance. So if the sample size is 14 very low, there was no evidence in the clinical 15 trial for a causal link to -- to POTS.</p> <p>16 But if the point estimate isn't low, you 17 shouldn't say that the incidence of the cases 18 associated with POTS was found to be extremely low. 19 Now, I could look up here exactly what was the 20 numbers because I don't report -- have that in my 21 report, but I think that was wrong.</p> <p>22 Q Let me ask -- let me ask you this, 23 Doctor. Did you -- do you agree that Merck has done 24 a careful review of the CRPS and POTS cases that 25 occurred as part of the clinical trials?</p>	<p style="text-align: right;">Page 197</p> <p>1 simple.</p> <p>2 A Okay.</p> <p>3 Q So let's try it again; okay?</p> <p>4 So turn to page five of your report. And 5 do you see there's a section PRAC question number 6 two?</p> <p>7 A Oh, okay. Yeah.</p> <p>8 Q Do you see that?</p> <p>9 A Yeah.</p> <p>10 Q Okay. And you say in your report, "Merck 11 [sic] has done a careful review of the CRPS and POTS 12 cases that occurred as part of the clinical trials."</p> <p>13 Do you see that?</p> <p>14 A I see that now, yes.</p> <p>15 Q You wrote that?</p> <p>16 A Yes.</p> <p>17 Q You stand by that?</p> <p>18 A Yes.</p> <p>19 Q Okay. In terms of the incidence of POTS 20 in the clinical trials, can you turn to page 13 21 of -- of this large --</p> <p>22 A Okay.</p> <p>23 Q -- report, Exhibit 26?</p> <p>24 A Okay.</p> <p>25 Q Now, in terms of the line of POTS, you</p>

50 (Pages 194 - 197)

<p style="text-align: right;">Page 198</p> <p>1 can see that there are two cases in 15,801 people; 2 correct? 3 A Yes. 4 Q Now, those people were actually in the 5 trial for a long -- a long time; right? 6 A I don't remember how long they were in 7 the trial, but they were in the trial. 8 Q Well, you can see that the person-years 9 of follow up is much greater than the actual number 10 of people; correct? 11 A Yeah. So they should have average have 12 been there for more than two years. 13 Q Right. And so the rate, when you use 14 person-years of follow up, is 0.5 per ten thousand 15 patient years; correct? 16 A Yes. 17 Q And that -- if we are doing easy math, 18 that is 50 per one hundred thousand; right? 19 I'm sorry. Withdrawn. 20 If we are doing -- maybe the math is not 21 so easy. Sorry. Withdrawn. 22 In terms of 0.5 per ten thousand 23 person-years, that equates to five per hundred 24 thousand patient-years; correct? 25 A It's five per hundred thousand, yes.</p>	<p style="text-align: right;">Page 200</p> <p>1 A Yeah. 2 Q One sentence in it says, "CDC and FDA 3 physicians, epidemiologists and statisticians assess 4 numbers of reports, types of reports based on 5 serious and non-serious status, the most common 6 adverse events, current versus historical data, and 7 reporting trends over time such as comparisons of 8 influenza vaccine reports across multiple 9 consecutive influenza seasons." 10 Do you see that? 11 A Yes. 12 Q Is it true that CDC and FDA have 13 physicians? 14 A Yes. 15 Q Is it true that they have 16 epidemiologists? 17 A Yes. 18 Q Is it true they have statisticians, like 19 yourself? 20 A They have statisticians. 21 Q I guess you are an individual, aren't 22 you? 23 Withdrawn. 24 The very next sentence says, "Analysis 25 also includes evaluation of reporting rates of</p>
<p style="text-align: right;">Page 199</p> <p>1 Q And that's 50 per million; correct? 2 A Yeah. 3 Q Okay. Now, if we can go back to 4 Exhibit 20, which is Shimabukuro 2015. Tell me -- 5 tell me when you've got that back up. 6 We've looked at it a bit. It's 7 Exhibit 20. 8 I suspect it's more on the top because we 9 talked about it fairly recently. 10 A Is it this one -- 11 Q No. 12 A No. 13 Maybe this one here. 14 Q Oh. 15 A This one here, yeah. 16 Q Wrong pile. 17 A Thank you for your patience. 18 Q That's okay. You've got -- withdrawn. 19 You've got Shimabukuro 2015 in front of 20 you; correct? 21 A Yes. 22 Q If you can turn to page 4401, there's a 23 section 6.1 at the bottom left. 24 A Okay. 25 Q Do you see that?</p>	<p style="text-align: right;">Page 201</p> <p>1 adverse events in the context of vaccine doses 2 distributed for use in the U.S. marketplace." 3 Do you see that? 4 A Yes. 5 Q So one of the things that the CDC and the 6 FDA do, is they look at reporting rates that come in 7 and then compare them to doses distributed; right? 8 A Okay. 9 Q Is that right? 10 That's what they say. 11 A Uh-huh. 12 Q You agree that's what they say; right? 13 A Yes. 14 Q Then it says, "Vaccine doses distributed 15 provides a proxy measure of number persons" -- I'm 16 sorry -- "of persons vaccinated. Reporting rates 17 enable comparison with background rates of adverse 18 events from the literature or other sources, but 19 they must be interpreted cautiously since vaccine 20 doses distributed might not all be administered." 21 Do you see that? 22 A Yes. 23 Q You agree with that? 24 A Very much so. 25 Q Okay. Thought we would.</p>

<p style="text-align: right;">Page 202</p> <p>1 A This also other reason is that sometimes 2 people get more than one dose so then you don't know 3 how many people were exposed because you don't know 4 how many got one dose, versus two of the doses, and 5 so on.</p> <p>6 Q And in terms of the EMA -- I'm sorry. 7 Withdrawn.</p> <p>8 In terms of the analysis that you 9 performed of Merck's responses to the EMA, you had 10 some discussion about their observed versus expected 11 analysis.</p> <p>12 A Yes.</p> <p>13 Q Correct?</p> <p>14 A I did.</p> <p>15 Q And can you confirm that the -- the EMA 16 actually asked Merck to conduct the observed versus 17 expected analysis?</p> <p>18 A I think they did. I don't remember if 19 they specified it during using spontaneous reports.</p> <p>20 Q If you look --</p> <p>21 A Because you can -- but maybe -- maybe. I 22 don't remember if they did that specifically or 23 not --</p> <p>24 Q Yeah.</p> <p>25 A -- so I have to look -- I could have to</p>	<p style="text-align: right;">Page 204</p> <p>1 Q Now, you had some criticisms, I thought, 2 in your report about the background rate that Merck 3 chose in connection with looking at POTS -- the POTS 4 background rate.</p> <p>5 Did -- did you have criticisms of that?</p> <p>6 A I have a criticism of those background 7 rates. In terms of Merck choosing it, I have to 8 give credit to the Merck that there wasn't really 9 anything good to choose between.</p> <p>10 Q Well --</p> <p>11 A So I can't really blame Merck for -- 12 for -- when there's nothing good available to pick, 13 so I can't really blame Merck for doing that.</p> <p>14 Q And my -- and my simple question to you 15 is going to be: To be clear, in your expert report 16 you did not cite a different background rate for 17 POTS that should have been used in 2015.</p> <p>18 Fair?</p> <p>19 A I'm not aware of anything there.</p> <p>20 So what I would have done is --</p> <p>21 Q Well, let me ask -- let -- let me get 22 those two not quite in the same thing because I need 23 a -- I'll ask you that.</p> <p>24 But first of all -- so withdrawn.</p> <p>25 You agree that in your expert report you</p>
<p style="text-align: right;">Page 203</p> <p>1 look that up.</p> <p>2 Q If you look at page 130 of that report, 3 and tell me when you are there?</p> <p>4 A Yeah.</p> <p>5 Q Is there a PRAC question three or is my 6 page numbering off?</p> <p>7 Do you see PRAC question three, 1.3 on 8 page 130? Yes?</p> <p>9 A Yes.</p> <p>10 Q And do you see that question from the 11 PRAC says, "The MAHs," that's Merck; right?</p> <p>12 A Yeah.</p> <p>13 Q "Merck [sic] should provide an analysis 14 of the observed number of post-marketing cases of 15 CRPS and POTS in association with their [HPV] 16 vaccine in comparison to those expected in the 17 target population, stratified by region, if 18 available."</p> <p>19 Do you see that?</p> <p>20 A Yes.</p> <p>21 Q I read that correctly; right?</p> <p>22 A Yup.</p> <p>23 Q And that's the question that PRAC -- that 24 PRAC asked; correct?</p> <p>25 A Yes.</p>	<p style="text-align: right;">Page 205</p> <p>1 did not cite a different background rate for POTS 2 that Merck should have used; correct?</p> <p>3 A That is correct.</p> <p>4 Q And then you wanted to say what you would 5 have done. And so I want to give you the 6 opportunity to say that.</p> <p>7 A Thank you.</p> <p>8 So it doesn't say in the question that 9 they have to use spontaneous report data. Because I 10 think, even if some other bit of background rate had 11 been available, it's hopeless to do any good 12 analysis use comparing spontaneous report with 13 background rates.</p> <p>14 So what would have been better to do 15 would have been to go to, for example, to Kaiser. 16 And from that data set, you can get -- instead of 17 using spontaneous reports, you can get the number of 18 POTS or CRPS after vaccine in the Kaiser data, and 19 then compare that to background rates also from the 20 Kaiser data.</p> <p>21 And then you can use exactly the same 22 definitions. You can compare apples to apples 23 instead of apples to oranges. So that would be what 24 I -- how I would have responded to this PRAC 25 question number three.</p>

<p style="text-align: right;">Page 206</p> <p>1 Q In connection with your expert report in 2 this case, on page eight, you state -- right above 3 question number five -- you state that Merck states 4 that there's no epidemiologic evidence for an 5 association between HPV vaccine and CRPS or POTS. 6 And then you go on to say, "yet there 7 were not proper studies at that time to evaluate 8 this association from an epidemiologic standpoint." 9 Do you see that, sir?</p> <p>10 A Yes.</p> <p>11 Q And the time frame we are talking about 12 here is 2015; correct?</p> <p>13 A Yes.</p> <p>14 Q And what -- what are proper studies in 15 your mind here?</p> <p>16 A There were no studies based on electronic 17 health records or health insurance claims data that 18 used medical short reviews to determine if the -- 19 the -- the proper definitions of the POTS. 20 So the studies that had been done, which -- which 21 raise sort of the major concerns about this, was 22 the -- the Chandler study or the Uppsala Monitoring 23 Centre studies, etc., where -- which had raised 24 these concerns.</p> <p>25 So there was no proper studies that had,</p>	<p style="text-align: right;">Page 208</p> <p>1 autoimmune diseases, but I would have to check just 2 to make sure.</p> <p>3 There wasn't --</p> <p>4 Q Okay.</p> <p>5 A There wasn't many things showing up. (Whereupon, Exhibit MK 27, Minutes and Responses to PRAC from the SAG Vaccines Meeting on HPV Vaccines (Article 20 Referral), was marked for identification.)</p> <p>11 BY MR. TOMASELLI:</p> <p>12 Q Okay. Exhibit 27 is a document dated 13 November of 2015 that is titled, "Minutes and 14 Responses to PRAC from the SAG Vaccines meeting on 15 HPV vaccines (Article 20 referral)"</p> <p>16 Do you see that, sir?</p> <p>17 A Yes.</p> <p>18 Q Have you ever seen these minutes from the 19 Scientific Advisory Committee from the Article 20?</p> <p>20 A No, I don't think I have.</p> <p>21 Q Okay. If you can turn to page four of 22 six, and tell me when you are there?</p> <p>23 A Okay. Hold on a second.</p> <p>24 Which page did you say?</p> <p>25 Q Four of six.</p>
<p style="text-align: right;">Page 207</p> <p>1 sort of, evaluate that hypothesis that -- that the 2 Uppsala Monitoring Centre had come up with.</p> <p>3 Q Was your Yih 2018 publication a proper 4 study?</p> <p>5 A It's a very proper study. I think it's a 6 very good study. But it's not a study to look at 7 POTS or CRPS.</p> <p>8 But you can have a very good study for 9 looking at, for example, does Gardasil cause stroke, 10 finding that there's no stroke. That can be 11 excellent, fantastic, really good study but it has 12 nothing to say about POTS or CRPS.</p> <p>13 Q There's, obviously, ICD-10 codes and 14 ICD-9 codes for a variety of autoimmune diseases; 15 right?</p> <p>16 A Yes.</p> <p>17 Q And neither of your publications, Yih 18 2018 or Yih 2021, provide any evidence for an 19 increased risk of Gardasil for any autoimmune 20 condition; correct?</p> <p>21 A I think --</p> <p>22 MR. BAUM: Objection. Vague.</p> <p>23 BY MR. TOMASELLI:</p> <p>24 Q Go ahead. You can answer.</p> <p>25 A I think it was -- none of them were for</p>	<p style="text-align: right;">Page 209</p> <p>1 A Okay.</p> <p>2 Q And if you look just about in the dead 3 middle of the page do you see a paragraph that 4 starts, "The observed/expected"?</p> <p>5 A Yes.</p> <p>6 Q That paragraph states, "The 7 observed/expected (O/E) analysis conducted by the 8 [MAH]... -- Manufacturer Authorization Holders, 9 which is Merck, right? -- "...in the frame of the 10 referral, and thoroughly assessed by the 11 Rapporteurs, seems to be as robust as it could be, 12 given the difficulties with the type of data 13 gathered and the assumptions made."</p> <p>14 Do you see that?</p> <p>15 A Yes.</p> <p>16 Q And if you go to the very last sentence 17 of the paragraph, it says, "However it was noted 18 that the O/E analysis [sic] covered a range of 19 scenarios taking into account uncertainties in both 20 the [sic] numerator and denominator, and the most 21 plausible scenarios showed no excess of POTS or CRPS 22 cases above the background rate considering the 23 situation in individual countries (e.g. completeness 24 of -- completeness and quality [of] reporting.)"</p> <p>25 Do you see that, sir?</p>

53 (Pages 206 - 209)

<p style="text-align: right;">Page 210</p> <p>1 A Yes, I see that.</p> <p>2 Q And to be clear, you've not seen these 3 minutes before; right?</p> <p>4 A I have not.</p> <p>5 Q And if you turn back to the first page of 6 this document, do you see that there's a list of 7 participants with respect to this Scientific 8 Advisory Group?</p> <p>9 A Yes.</p> <p>10 Q And you can go and count them up, but 11 there's, you know, over 30 people that are involved 12 in this -- in this review; right?</p> <p>13 A Yeah. I mean, approximately, yes.</p> <p>14 Q Yeah. And do you know any of the 15 Scientific Advisory Group vaccine core members or 16 additional experts or the PRAC rapporteurs and 17 assessors? Do you know any of these people?</p> <p>18 A Do you know mean if I know them 19 personally? I met them? Or if I've communicated 20 with them or if I know of them?</p> <p>21 Q Well, just start with that you know them 22 personally?</p> <p>23 A I think I have met Hanna Nohynek, maybe. 24 But that would be the only one who I think I might 25 have met personally. And I'm not a hundred percent</p>	<p style="text-align: right;">Page 212</p> <p>1 All right. Well, later.</p> <p>2 A Do you want to take a break so you can 3 find it?</p> <p>4 Q No. We got plenty to do.</p> <p>5 So -- withdrawn.</p> <p>6 I want to talk about Dr. Tomljenovic's 7 disproportionality analysis, if we can --</p> <p>8 A Okay.</p> <p>9 Q -- for a little bit; okay?</p> <p>10 Now, she analyzed the VAERS data set; 11 right?</p> <p>12 A I believe so, yeah.</p> <p>13 Q And it looks like that she, based on your 14 report, that she looked at different time periods. 15 For example, some of her analyses were up to 2015 16 and some of them went up through today, 2024?</p> <p>17 A Yup.</p> <p>18 Q And did you make any effort to understand 19 the number of Gardasil doses that had been 20 distributed at either of those times, 2015 or 2024?</p> <p>21 A I don't think that's relevant for the 22 disproportionality analysis.</p> <p>23 Q Okay. And in terms of the 24 disproportionality analysis, it looked like there 25 were about 60 cases of POTS through 2015, and maybe</p>
<p style="text-align: right;">Page 211</p> <p>1 sure.</p> <p>2 She's from Finland.</p> <p>3 Q Okay. Now, you're aware -- again, we 4 looked at the report, the assessment report, but 5 that was from November of 2015; right?</p> <p>6 A This one is from November 2015, yes.</p> <p>7 Q And are you aware, after November of 8 2015, whether any member state of the European Union 9 asked Merck to redo any of the analyses in Article 10 20? Are you aware of that or not?</p> <p>11 A I know there was some concerns about this 12 review from some people in Denmark but I don't know 13 if there was a formal request from the Danish 14 authorities or not.</p> <p>15 Q Well, that's my question. Do you know 16 whether the Danish Health Authority ever asked Merck 17 to redo any analysis related to the Article 20 18 procedure?</p> <p>19 A I don't know.</p> <p>20 Q Okay. Do you know whether the EMA or any 21 of the scientific Advisory Group members ever asked 22 Merck to redo any analysis?</p> <p>23 A I'm not aware of any such request.</p> <p>24 Q Oh, you might be in luck. I can't find 25 it.</p>	<p style="text-align: right;">Page 213</p> <p>1 less than a 400 overall for 2024; correct?</p> <p>2 A I would have to look to confirm or not, 3 but I don't -- I won't dispute it.</p> <p>4 Q There was no clinical review of the cases 5 that -- that were identified by her search; correct?</p> <p>6 A That's correct.</p> <p>7 Q That is, no physician came in behind and 8 said, You know, I've taken a look at this report and 9 it either meets or doesn't meet the diagnostic 10 criteria for POTS or some other disease. No one did 11 that.</p> <p>12 A Well -- well, clinical review is when you 13 look at the specific VAERS report from a particular 14 patient and you say, Okay, does this fulfill the 15 criteria for POTS or not?</p> <p>16 That's the clinical review of the VAERS 17 reports.</p> <p>18 Q Okay. And no one did that with respect 19 to her analysis; correct?</p> <p>20 A That is my understanding, that that 21 wasn't done as part of this analysis, which is sort 22 of consistent with the -- the disproportionality 23 reporting done by CDC, who didn't do that either for 24 their disproportionality analysis.</p> <p>25 (Whereupon, Exhibit MK 29, Paper by</p>

54 (Pages 210 - 213)

<p style="text-align: right;">Page 214</p> <p>1 Arana, 2017, was marked for 2 identification.)</p> <p>3 BY MR. TOMASELLI:</p> <p>4 Q Well, you mentioned, Dr. Kulldorff, 5 earlier today that you were aware of the FDA and 6 CDC's analysis of POTS in 2017 that was -- that was 7 performed; correct?</p> <p>8 A Which paper is that?</p> <p>9 Q I'm handing you what I've marked as 10 Exhibit number 29, which is a paper by Arana and 11 others --</p> <p>12 MR. BAUM: This -- it --</p> <p>13 MR. TOMASELLI: It should be 2017. 14 Did I hand you 2017?</p> <p>15 MR. BAUM: No. No. No. I -- I got 16 the --</p> <p>17 THE WITNESS: This looks like 2017.</p> <p>18 MR. BAUM: You've been 19 characterizing it as a CDC study, but is 20 it actually sponsored and conducted by 21 the CDC?</p> <p>22 BY MR. TOMASELLI:</p> <p>23 Q Withdrawn.</p> <p>24 Dr. Kulldorff, I've handed you Exhibit 25 Number 29, which is a paper that was published in</p>	<p style="text-align: right;">Page 216</p> <p>1 actually.</p> <p>2 Q Okay. In this paper from 2017 with 3 Arana, they actually did an analysis of the VAERS 4 database for POTS; correct?</p> <p>5 A Yes. This was specifically regarding 6 POTS.</p> <p>7 Q This is the article that you were aware 8 of that we talked about earlier; right?</p> <p>9 A Yes. So I cite this in my report.</p> <p>10 Q Okay. And if we go to page two, right 11 column, do you see, "Review of POTS reports...?"</p> <p>12 A Yes.</p> <p>13 Q It says, "CDC and FDA physicians reviewed 14 POTS reports following HPV vaccination (and medical 15 records if available) identified in the initial 16 VAERS database search."</p> <p>17 Do you see that?</p> <p>18 A Yes.</p> <p>19 Q So you can confirm that, at least as 20 reported in this article, the physician reviewers 21 did review not only the reports but medical records 22 if they were available?</p> <p>23 A Okay. Yes.</p> <p>24 So I must have been wrong before then 25 because I guess they did it for some of them but not</p>
<p style="text-align: right;">Page 215</p> <p>1 2017, by the first author of Arana; correct?</p> <p>2 A Yes, you have.</p> <p>3 Q And in connection with Jorge Arana, he 4 was affiliated with the CDC at this time; correct?</p> <p>5 A Yes. I think all authors are either from 6 the CDC or FDA. They do have a disclaimer that the 7 findings and conclusions in this report are those of 8 the authors and do not necessarily represent the 9 official positions of the CDC or the FDA.</p> <p>10 Q They put that in every one of their 11 papers, basically; correct?</p> <p>12 A Pretty much.</p> <p>13 Q Yeah. And this person with the FDA, this 14 Adamma Mba-Jonas?</p> <p>15 A Yes.</p> <p>16 Q Do you see that name?</p> <p>17 A Yes.</p> <p>18 Q That's A-d-a-m-m-a, and then last name, 19 M-b-a, dash, J-o-n-a-s.</p> <p>20 Correct?</p> <p>21 A Yes.</p> <p>22 Q You've published with her.</p> <p>23 A Yes.</p> <p>24 Q She's a good researcher; right?</p> <p>25 A I haven't worked closely with her,</p>	<p style="text-align: right;">Page 217</p> <p>1 for all of them.</p> <p>2 Q And the conclusion of this paper, if you 3 go to the very last statement on the last page -- 4 and tell me when you are there. 582, the very last 5 page?</p> <p>6 A Yes.</p> <p>7 Q The very last sentence of these people 8 that work at the CDC and the FDA state that, "Our 9 safety review did not detect any unusual or 10 unexpected patterns of reporting for POTS following 11 HPV vaccination."</p> <p>12 Do you see that?</p> <p>13 A I see that.</p> <p>14 Q Okay.</p> <p>15 A So --</p> <p>16 Q Well --</p> <p>17 A -- one thing --</p> <p>18 Q -- let me --</p> <p>19 A -- that's important with this paper is 20 that they did two things. They did the reviews of 21 the things, and then they also did something called 22 empirical-based data mining. So that's the 23 disproportionality analysis.</p> <p>24 And it's my understanding that for the 25 empirical-based data mining, they did not use any</p>

<p style="text-align: right;">Page 218</p> <p>1 clinical reviews. That would have been wrong to do 2 it because they did clinical reviews of the post 3 cases following the Gardasil vaccines, but to do 4 a -- to do empirical-based data mining, they would 5 have to then do it also on all the other 6 vaccinations, the control group for other vaccines. 7 So therefore, when they did the 8 empirical-based data mining, they could not utilize 9 the -- the clinical review they did, and they have 10 to do that on the data that was not reviewed. 11 So it's my understanding -- it's not a 12 hundred percent clear what they did in the paper -- 13 but it's my understanding that they -- for the 14 disproportionality analysis, using this 15 empirical-based data mining, they did not do that 16 clinical review. 17 Also, one complaint I have about this 18 paper is that they are specific -- they are 19 evaluating a specific hypothesis, which is POTS 20 after Gardasil. Data mining is something you use if 21 you don't have a prespecified hypothesis, you are 22 looking for hundreds of thousands of different 23 things, and data mining is very good for that. 24 But if you -- in that -- like in this 25 case, you have a very specific hypothesis, you</p>	<p style="text-align: right;">Page 220</p> <p>1 and those who got the other vaccine because that's 2 critical that you do it identical. 3 Even if it's a little bit off somewhere, 4 the key thing is that you do it the same for both 5 groups so you are comparing apples to apples. 6 Q Did you ever rerun her searches in the 7 VAERS database? 8 A No. 9 Q Have you ever personally queried the 10 VAERS database or run searches in it? 11 A No. 12 Q Did you verify her counts or the events 13 that make up her counts? 14 A No. 15 Q Is Dr. Tomljenovic's disproportionality 16 analysis, that you are aware, either published or 17 peer reviewed other than by you? 18 A It's not published. I did a peer review 19 of it. 20 Q You are -- you are not vouching for her 21 as a researcher generally, are you? 22 For example, you are vouching for the 23 analysis that she did in her 2024 report but you are 24 not vouching just generally as her as a researcher; 25 correct?</p>
<p style="text-align: right;">Page 219</p> <p>1 should never use data mining approach because then 2 you are over compensating for multiple testing 3 that's not there. So that's sort of an artificial 4 way of not finding things. 5 So they should not have used data mining 6 methods that adjust for the multiple testing, which 7 they did. They should have just sort of reported it 8 more straight. 9 Q Dr. Kulldorff, in terms of 10 Dr. Tomljenovic's disproportionality analysis, did 11 you -- did you assess the adequacy of the terms that 12 she used to query the database? 13 A Of the who? 14 Q The disproportionality analysis -- 15 A Yeah. 16 Q -- that you reviewed for 17 Dr. Tomljenovic -- 18 A Okay. 19 Q -- did you assess yourself the adequacy 20 of the -- of the terms used to query the database? 21 A No. That's not my expertise because I 22 don't have the clinical expertise to do that. 23 Q And -- 24 A I just asserted that they were -- they 25 used the same for those who got the Gardasil vaccine</p>	<p style="text-align: right;">Page 221</p> <p>1 A I -- I was asked to evaluate this 2 particular report, her expert report, but only even 3 part of it, which is the proportional reporting or 4 the reporting odds ratios in section four of her 5 report. So that is what I did. 6 Q Good point. 7 A And -- 8 Q You did not attempt to verify her whole 9 expert report; correct? 10 A Correct. 11 Q Okay. 12 A I haven't even read the whole of it, 13 so... 14 Q And you are not aware, one way or the 15 other, whether she's had multiple publications 16 withdrawn from the medical literature; right? You 17 don't know one way or the other? 18 A No. 19 Q Okay. And we -- well, let me ask you 20 this -- withdrawn. 21 Prior to ever reviewing her report 22 related to disproportionality of POTS or POI, did 23 you search the medical literature to see if previous 24 disproportionality analyses related to POTS or POI 25 or those types of symptoms were performed?</p>

<p style="text-align: right;">Page 222</p> <p>1 A I looked at other -- I was aware of some 2 of those before. Like the Rebecca Chandler, I've 3 been aware of that work since it came out, more or 4 less.</p> <p>5 And I looked for others. And, for 6 example, the Arana paper was one of them --</p> <p>7 Q So --</p> <p>8 A -- that I found.</p> <p>9 Q Okay. So -- and -- and -- I think we 10 talked about earlier that the -- the EMA has a 11 disproportionality analysis in their assessment 12 report in 2015; right?</p> <p>13 A That's the one from Uppsala Monitoring 14 Centre?</p> <p>15 Q That's right.</p> <p>16 A I don't think they did some on their own, 17 do they?</p> <p>18 Q Say again?</p> <p>19 A They -- they talk about the one from 20 Uppsala Monitoring Centre.</p> <p>21 Q So let me try again.</p> <p>22 In terms of disproportionality analyses 23 that were performed we agree that the Uppsala 24 Monitoring senator -- Centre had one that they 25 provided the EMA, that the EMA reviewed in 2015;</p>	<p style="text-align: right;">Page 224</p> <p>1 you?</p> <p>2 A I didn't prepare that so --</p> <p>3 Q Okay. Do you remember a paper Bunaldo 4 2019?</p> <p>5 A Bunaldo?</p> <p>6 Q Yes. If you don't, you don't.</p> <p>7 A There was a Maldonado (phonetic), I 8 think. But that's a different one, no?</p> <p>9 Q It's different.</p> <p>10 A Well, there's a -- and then there's the 11 Shimabukuro's, with the -- with the 12 disproportionality analysis --</p> <p>13 Q Okay.</p> <p>14 A -- for --</p> <p>15 Q So try to --</p> <p>16 A -- for Gardasil.</p> <p>17 Q -- shortcut this a little bit.</p> <p>18 We can agree -- withdrawn.</p> <p>19 We can agree that there were four or five 20 separate disproportionality analyses related to POTS 21 or POTS-like symptoms that were published in the 22 medical literature prior to you taking a look at 23 Dr. Tomljenovic's disproportionality analysis; 24 right?</p> <p>25 A There was a number of them on Gardasil,</p>
<p style="text-align: right;">Page 223</p> <p>1 right? We've looked at that?</p> <p>2 A Yes.</p> <p>3 Q Okay. And then we have the Chandler, 4 excuse me, publication that you talked about; right?</p> <p>5 Yes?</p> <p>6 A The one with the cluster thing?</p> <p>7 Q That's right.</p> <p>8 A Yeah. And there's, I think, at least one 9 other one, also.</p> <p>10 Q And you just mentioned Arana is --</p> <p>11 A Yeah.</p> <p>12 Q -- a disproportionality analysis; 13 correct?</p> <p>14 Yes?</p> <p>15 A Yes.</p> <p>16 Q And I saw in your materials considered 17 list a publication by Bunaldo (phonetic) in 2019.</p> <p>18 Does that ring a bell?</p> <p>19 A Which number is that?</p> <p>20 Q Forty-five.</p> <p>21 A "Safety profile of human papilloma virus 22 vaccines," which one is that? Which paper is that?</p> <p>23 Who is the author?</p> <p>24 Q You conveniently left them off so I'm 25 asking you. Just -- you didn't prepare that, did</p>	<p style="text-align: right;">Page 225</p> <p>1 and some of those dealt with POTS. And others -- 2 the others I think did not deal with POTS.</p> <p>3 Q Can we also agree that there were also 4 disproportionality an- -- disproportionality 5 analyses related to POI in the medical literature 6 published and peer reviewed prior to you taking a 7 look at her disproportionality analysis in 2024?</p> <p>8 A I believe so, yeah.</p> <p>9 MR. TOMASELLI: My colleague is 10 earning his money over here, doing a 11 great job.</p> <p>12 All right. Withdrawn.</p> <p>13 (Whereupon, Exhibit MK 28, Article by 14 Patricia Wodi, was marked for 15 identification.)</p> <p>16 BY MR. TOMASELLI:</p> <p>17 Q Exhibit 28 -- sorry, I skipped 28 18 earlier -- but Exhibit 28 is an article by Patricia 19 Wodi, W-o-d-i.</p> <p>20 Do you see that?</p> <p>21 A Yes.</p> <p>22 Q Okay. And these authors are also, some 23 of them, affiliated with the CDC and the FDA; 24 correct?</p> <p>25 A Yes.</p>

<p style="text-align: right;">Page 226</p> <p>1 Q And have -- have you seen this -- this 2 paper before?</p> <p>3 A I have, yes.</p> <p>4 Q Okay. So you're aware that the FDA and 5 the CDC have analyzed disproportionality of 6 reporting relating to POI prior to your review of 7 Dr. Tomljenovic's analysis; correct?</p> <p>8 A Yes.</p> <p>9 And it says here, on page five, "Data 10 mining.</p> <p>11 "There were three vaccine-event pairs 12 reported at least twice as often as expected among 13 female or unknown sex with all three reported 14 following HPV vaccination (Gardasil). We observed 15 disproportionate reporting for the PTs Amenorrhea, 16 Premature Menopause, and Infertility Female."</p> <p>17 So this seems that there was some kind of 18 axis that they observed here that were somewhat 19 related to POI here.</p> <p>20 Q Exactly, sir.</p> <p>21 The --</p> <p>22 A But it doesn't say, actually -- it -- it 23 doesn't -- I don't think it gives actual number, 24 like the point estimates or the confidence 25 intervals, they just have these two sentences on</p>	<p style="text-align: right;">Page 228</p> <p>1 paragraph, yes.</p> <p>2 Q Okay. And that paragraph says, "An FDA 3 physician who is board-certified in gynecology 4 conducted an independent review of all POI cases 5 identified by CDC physicians to adjudicate if each 6 POI case was a 'Confirmed POI,' 'Possible POI,' or 7 'Not POI,' using the guidelines above."</p> <p>8 Do you see that?</p> <p>9 A Yes.</p> <p>10 Q And as you mentioned earlier, they did 11 find -- withdrawn.</p> <p>12 As you mentioned earlier, the FDA 13 observed -- I'm sorry. Withdrawn.</p> <p>14 As you noted earlier, the Wodi authors 15 observed disproportionate reporting for the 16 preferred terms of amenorrhea, premature menopause, 17 and infertility female; correct?</p> <p>18 A Correct.</p> <p>19 Q Now, did you also see where they 20 discussed a study by Gong that is a data mining 21 analysis?</p> <p>22 A Where is that?</p> <p>23 Q So if you go to the page 1620, bottom 24 right -- or is there not page --</p> <p>25 A I have --</p>
<p style="text-align: right;">Page 227</p> <p>1 data mining.</p> <p>2 And -- and that's the disproportionality 3 analysis that they did.</p> <p>4 Q Okay. So a couple things. Number one, 5 this is a disproportionality analysis in VAERS; 6 right?</p> <p>7 A This was VAERS data, yes.</p> <p>8 Q And it relates to POI as well as other 9 preferred terms that are -- that -- that are similar 10 in terms of POI or that could reflect potentially 11 POI; right?</p> <p>12 A Some relationship to it, yes.</p> <p>13 Q Yeah. And under clinical review of 14 reports, under 2.2 on page two, 2.2 page two, you 15 can see that they say, "Each report (including any 16 available medical records) was manually reviewed by 17 CDC physicians."</p> <p>18 Do you see that?</p> <p>19 A Correct.</p> <p>20 Q And then below -- if you go below in that 21 same column, right above "Data mining," do you see, 22 "An FDA physician"?</p> <p>23 Do you see that? My simple question is 24 are you with me?</p> <p>25 A Yes. I'm on the location in that</p>	<p style="text-align: right;">Page 229</p> <p>1 Q -- numbers on --</p> <p>2 A -- I have --</p> <p>3 Q -- them?</p> <p>4 A -- pages one and so on.</p> <p>5 Q All right. Let me just see. Sorry. 6 Apologies.</p> <p>7 Yup. Bottom right of the page I'm 8 handing you, Dr. Kulldorff.</p> <p>9 A Thank you.</p> <p>10 MR. BAUM: What's -- what is the 11 page number on the bottom right?</p> <p>12 THE WITNESS: Five.</p> <p>13 MR. TOMASELLI: Sorry, Michael.</p> <p>14 MR. BAUM: It's okay.</p> <p>15 MR. TOMASELLI: I've got a different 16 copy.</p> <p>17 MR. BAUM: Oh.</p> <p>18 MR. TOMASELLI: So it's --</p> <p>19 MR. BAUM: Okay.</p> <p>20 MR. TOMASELLI: -- probably --</p> <p>21 BY MR. TOMASELLI:</p> <p>22 Q Withdrawn --</p> <p>23 In the bottom right-hand column of this 24 paper, the last five lines of the pa- -- of this 25 column say, "Similar to the study by Gong, et al.,</p>

<p style="text-align: right;">Page 230</p> <p>1 data mining in our study observed disproportionate 2 reporting of POI related [to preferred terms] [sic] 3 in VAERS compared to other vaccines."</p> <p>4 Do you see that?</p> <p>5 A Yes.</p> <p>6 Q Were you aware of the Gong paper?</p> <p>7 A I don't believe I read the Gong paper.</p> <p>8 Q Okay. They go on to say, "However, 9 compared to Gong, et al., our study included 10 clinical review of VAERS report and medical records 11 if available."</p> <p>12 Do you see that?</p> <p>13 A Yes.</p> <p>14 Q And if you go to the next page at the 15 top -- well, I should probably start on the page 16 before. It says "although" on the page before.</p> <p>17 "Although majority of reports identified 18 in our study noted receipt of HPV vaccines (with or 19 without other vaccines) [sic], clinical review 20 determined that the AEs contained in most reports 21 were either pregnancy-related, (such as amenorrhea 22 dur-) [sic]" -- "(due to pregnancy) [sic], hearsay 23 reports, or also noted the presence of other 24 conditions that cause symptoms similar to POI such 25 as pituitary pathology and polycystic ovary</p>	<p style="text-align: right;">Page 232</p> <p>1 primary ovarian insufficiency; the person is just 2 pregnant?</p> <p>3 A So a -- a clinical review can determine 4 that some of the cases may be unrelated to the 5 vaccine under study.</p> <p>6 At the same time, when you do the 7 disproportionality analysis -- which I did here, the 8 data mining -- either you have to do that clinical 9 review on everybody -- both those with the Gardasil 10 vaccine and other vaccines, or you do it on neither.</p> <p>11 My understanding here is not explicitly 12 stated. But my understanding here is that when they 13 did the data mining, they did not use the clinical 14 reviews. Because they did the clinical reviews on 15 the people with Gardasil. They didn't do the 16 clinical review on the comparison group of other 17 vaccines.</p> <p>18 So when you do that disproportionality 19 analysis then, then, you -- then, you can have some 20 sort of false positive in the sense that they are 21 clearly due to something else. And you will have 22 that in both groups. So that, sort of, cancels each 23 other out when you do the disproportionality 24 analysis.</p> <p>25 (Whereupon, Exhibit MK 30, Paper by</p>
<p style="text-align: right;">Page 231</p> <p>1 syndrome."</p> <p>2 Do you see that?</p> <p>3 A Yes.</p> <p>4 Q And that's not news to you, that, of 5 course -- if a physician looks at a report of 6 amenorrhea or menstrual a- -- "aregularity," it 7 actually could be just that the person is pregnant; 8 right?</p> <p>9 A Well, I'm not a physician, so I'm not 10 going to give you any clinical reviews.</p> <p>11 Q Okay. You're aware that, just from 12 having daughters and whatever, that girls, you know, 13 have amenorrhea when they're pregnant; right?</p> <p>14 A Well, my daughter hasn't been pregnant 15 yet. She's eight years old.</p> <p>16 Q Okay.</p> <p>17 A So...</p> <p>18 Q Well, you've had a daughter.</p> <p>19 So do you have any other experience that 20 would lend a hand there?</p> <p>21 All right. Withdrawn.</p> <p>22 Would you agree that, just as a general 23 standpoint, clinical review can identify issues 24 within the reports that suggest, Okay, this is -- 25 this is not a case of premature infertility or</p>	<p style="text-align: right;">Page 233</p> <p>1 Tatang, was marked for 2 identification.)</p> <p>3 BY MR. TOMASELLI:</p> <p>4 Q Dr. Kulldorff, I'm going to hand you what 5 I've marked as Exhibit 30, which is a paper by 6 Tatang, T-a-t-a-n-g, in 2021; do you see that?</p> <p>7 A Yes.</p> <p>8 Q Have you seen this paper before?</p> <p>9 A I believe I have. Yes.</p> <p>10 Q Okay. And so this is another paper that 11 was in the medical literature discussing 12 disproportionality of reporting for POI prior to you 13 undertaking an analysis of Dr. Tomljenovic's 14 disproportionality --</p> <p>15 A Yes.</p> <p>16 Q -- analysis?</p> <p>17 Okay. By the way, do you -- if you turn 18 to -- if you turn to the third to last page --</p> <p>19 A The --</p> <p>20 Q -- right above the "Conclusion" --</p> <p>21 A Okay.</p> <p>22 Q -- you see there's a paragraph above the 23 conclusion, sir?</p> <p>24 A Yes.</p> <p>25 Q It says, "Finally, VAERS cannot be used</p>

<p style="text-align: right;">Page 234</p> <p>1 to determine whether a vaccine caused an AE as it 2 could be due to chance, confounders, or bias."</p> <p>3 Do you see that?</p> <p>4 A Yes.</p> <p>5 Q That's what the authors of Tatang said?</p> <p>6 A Yup.</p> <p>7 Q Correct?</p> <p>8 A Yup.</p> <p>9 Q "Therefore" -- they go on to say, 10 "Therefore, this study only generated the hypothesis 11 that there may be a signal of disproportionate 12 reporting for POF events and HPV vaccine that 13 warrants further investigation."</p> <p>14 Do you see that?</p> <p>15 A Yes.</p> <p>16 Q Okay. So similar to POTS and POTS-like 17 symptoms, there were numerous disproportionality 18 reports in the medical literature that were 19 peer-reviewed prior to you undertaking your analysis 20 of Dr. Tomljenovic's disproportionality analysis; 21 correct?</p> <p>22 A Correct.</p> <p>23 Q We talked about reporting bias before. 24 And do you agree that parental concerns 25 can be a source of reporting bias?</p>	<p style="text-align: right;">Page 236</p> <p>1 sources; and number two, can be reported by a number 2 of people?</p> <p>3 A Yes.</p> <p>4 Q Okay. Now, based on your experiences, 5 conversations around vaccine recommendations and 6 mandates can generate a significant amount of 7 publicity; true?</p> <p>8 A Yes.</p> <p>9 (Whereupon, Exhibit MK 31, Article by 10 Slade, et al., was marked for 11 identification.)</p> <p>12 BY MR. TOMASELLI:</p> <p>13 Q Dr. Kulldorff, I'm handing you Exhibit 14 31, which is a article by Slade and others from 15 2009; do you see that?</p> <p>16 A Yes.</p> <p>17 (Whereupon, there was a discussion 18 off the record.)</p> <p>19 BY MR. TOMASELLI:</p> <p>20 Q These are, again, authors affiliated with 21 the CDC and FDA; true?</p> <p>22 A I -- several of those names, I recognize 23 as CDC or FDA agents. Yes.</p> <p>24 Q And this is an analysis of the VAERS 25 database from June of '06 through December of '08,</p>
<p style="text-align: right;">Page 235</p> <p>1 A Parental concerns, when you have media 2 attention to something, that could generate 3 reporting bias or create bor- -- reporting bias.</p> <p>4 Q News --</p> <p>5 A Yeah.</p> <p>6 Q -- news coverage of potential adverse 7 events, or otherwise, can re- -- can create a 8 reporting bias; correct?</p> <p>9 A It can create re- -- the people sending 10 in reports which then generate the reporting bias, 11 yes.</p> <p>12 And that's not just parents. I think 13 physicians are also prone to -- to -- to do that.</p> <p>14 So --</p> <p>15 Q Fair.</p> <p>16 A -- I don't --</p> <p>17 Q Yeah.</p> <p>18 A -- I don't want to just blame the -- the 19 parents.</p> <p>20 Q No. And I didn't want to --</p> <p>21 A Yeah.</p> <p>22 Q -- either.</p> <p>23 I -- I -- I was -- I -- I was really just 24 getting to the point that that reporting bias, 25 ultimately, can come, number one, from a variety of</p>	<p style="text-align: right;">Page 237</p> <p>1 the first two and a half years of marketing of 2 Gardasil; correct?</p> <p>3 A That looks light it. Yeah.</p> <p>4 Q If you turn to page 756, and tell me when 5 you are there.</p> <p>6 A Yeah.</p> <p>7 Q They -- there's a three-column page here. 8 And in the middle column toward the 9 bottom, do you see that it says, "Although VAERS 10 shares inherent limitations of all passive 11 surveillance systems, it is national in scope and 12 can provide important signals that may require 13 further attention."</p> <p>14 Do you see that?</p> <p>15 A Correct.</p> <p>16 Q All right. And it goes on to say, "In 17 addition, data limitations include underreporting, 18 inconsistency in the quality and completeness of 19 reported data, stimulated reporting due to excessive 20 [sic] news coverage, and reporting biases."</p> <p>21 Do you see that?</p> <p>22 A Yes.</p> <p>23 Q And that's true; right?</p> <p>24 That's what we've been talking about?</p> <p>25 A That they can be stimulated reporting due</p>

60 (Pages 234 - 237)

<p style="text-align: right;">Page 238</p> <p>1 to excessive or due to news coverage and reporting 2 bias, I think that's true. 3 Whether you want to call it excessive or 4 not, that's a judgment call. 5 Q Fair enough. 6 Do you see, then, the next sentence says, 7 "The VAERS reporting rate for [Gardasil] [sic] is 8 triple the rate for all other vaccines combined"? 9 Do you see that? 10 A Yes. 11 Q So just in the first two-and-a-half years 12 of the marketing of Gardasil, there were three times 13 the number of reports into VAERS compared to the 14 whole other vaccines combined; right? 15 A Uh-huh. 16 Q Okay. That -- that's a lot of reporting; 17 right? 18 A Yeah. 19 So if there is an excess reporting like 20 that, that doesn't effect -- that doesn't 21 necessarily reflect the -- a -- a disproportionality 22 analysis, because that adjust for the fact if 23 reporting is high in general. 24 So the thing that -- to be care- -- 25 careful about with reporting bias is, if there is</p>	<p style="text-align: right;">Page 240</p> <p>1 approval by the U.S. [Food and Drug Administration] 2 [sic] (FDA) [sic] in 2006, Merck's human papilloma 3 virus vaccine [(HPV)] [sic] Gardasil has been 4 sparking controversy." 5 Do you see that? 6 A Yup. Yes. 7 Q Are you aware what controversy that is? 8 A I think one of the earlier issues were 9 the VTE, that there were hypothesis that they might 10 be causing VTE. 11 Q What about -- what about that it affected 12 fertility? 13 Are you aware of that? 14 A I don't remember that. I might have read 15 about that. 16 Q Again, and -- 17 A The other -- 18 Q -- that is -- 19 A -- the other thing was -- 20 Q We talked earlier, you did not actually 21 look into all these issues related to reporting 22 bias. In your report, you said, It's difficult to 23 judge. 24 But I thought we agreed that you actually 25 didn't look into all of the reasons for potential</p>
<p style="text-align: right;">Page 239</p> <p>1 media attention on a specific outcome -- whether it 2 is VTE or POTS or whatever it is -- that is what 3 will create the reporting bias. 4 So a large volume or a low volume, in 5 itself, does not necessarily create the reporting 6 bias. It's if it's differential by the outcomes. 7 Q I understand. 8 But it does suggest that there was a lot 9 of media attention or other attention that 10 stimulated reporting related to Gardasil; true? 11 MR. BAUM: Objection. Assumes facts 12 not in evidence. Speculation. 13 A I don't know. 14 BY MR. TOMASELLI: 15 Q You don't know. 16 (Whereupon, Exhibit MK 32, 2012 17 Article by Dr. Tomljenovic and Dr. 18 Shaw, was marked for identification.) 19 BY MR. TOMASELLI: 20 Q I'm going to mark as Exhibit 32 an 21 article by Dr. Tomljenovic and Shaw from 2012. 22 Do you see that? 23 A Yes. 24 Q Do you see in the introduction, the very 25 second sentence says, "Ever since its Fast Track</p>	<p style="text-align: right;">Page 241</p> <p>1 reporting bias; right? 2 A I don't think I said exactly that thing. 3 I mean, another controversy -- early 4 controversy of the HPV vaccine was people who felt 5 that this was given to -- it's a sex- -- sexual -- 6 it's -- it's for a sexually-transmitted virus. 7 And then, some people were upset that it 8 was given to their young girls who were not just 9 sexually active. So why would you give it to them? 10 So there was, sort of, the more moral 11 issues that some people were con- -- that was one 12 reason why this was, sort of, a -- a controversy of 13 this vaccine. 14 So that has nothing to do with potential 15 adverse reaction. It was just, sort of, the -- the 16 fact that it was for a sexual transmitted disease 17 and given to young girls, which, by the way, I don't 18 agree with that concern. So... 19 Q 'Cause it's not borne by the data; right? 20 You're aware there's five or six studies 21 showing that -- that the -- the -- the provision of 22 Gardasil vaccine has absolutely nothing to do with 23 sexual debut; correct? 24 You're aware of that data? 25 A That's possible. I don't -- I have no</p>

<p style="text-align: right;">Page 242</p> <p>1 idea. But --</p> <p>2 Q The data on it?</p> <p>3 A -- but the point is that you want to give</p> <p>4 the vaccine before -- before people are exposed to</p> <p>5 the virus.</p> <p>6 Q Now, we agreed earlier that some of her</p> <p>7 analyses include data up to 2024; correct?</p> <p>8 A Yes.</p> <p>9 Q That would necessarily include every</p> <p>10 lawsuit alleging POTS in the country; right?</p> <p>11 MR. BAUM: Objection. Assumes facts</p> <p>12 not in evidence. Speculation.</p> <p>13 A I'm not quite sure what you mean by the</p> <p>14 question.</p> <p>15 BY MR. TOMASELLI:</p> <p>16 Q Well, I mean, manufacturers have to</p> <p>17 report adverse events with their product.</p> <p>18 And a lawsuit alleging POTS due to</p> <p>19 Gardasil is an adverse event relating to their</p> <p>20 product, and that gets into VAERS, doesn't it?</p> <p>21 A Yes. Merck is, by law, obliged to report</p> <p>22 any things that they -- any- -- any of the things</p> <p>23 that's reported to them, they have to report it to</p> <p>24 VAERS by law. Yeah.</p> <p>25 Q Right.</p>	<p style="text-align: right;">Page 244</p> <p>1 Gardasil. So if the incidence is flat, it doesn't</p> <p>2 matter what other age of -- for the two vaccines.</p> <p>3 If the two vaccines are the same, it</p> <p>4 doesn't matter what -- what the age distribution is</p> <p>5 for the -- for the outcome. They, sort of, cancel</p> <p>6 each other out.</p> <p>7 But if all three of these are different,</p> <p>8 you are going to have some bias. It can go in</p> <p>9 either direction.</p> <p>10 Q Let me -- let me -- let me ask you this.</p> <p>11 A Yeah.</p> <p>12 Q Did you ever suggest to Dr. Tomljenovic</p> <p>13 that she remove six-, seven-, and eight-year-olds</p> <p>14 from her VAERS analysis?</p> <p>15 A So I suggested that she should not go all</p> <p>16 the way from 6 to 20-something, because that gives</p> <p>17 more.</p> <p>18 Now, she -- what she said that she --</p> <p>19 the -- the data wasn't available by age. So if you</p> <p>20 had the exact age for each person, then, you can</p> <p>21 actually do the reporting odds ratio adjusted for</p> <p>22 age.</p> <p>23 Q Yeah.</p> <p>24 A And then, it doesn't matter if you</p> <p>25 include 6-to-8 or not --</p>
<p style="text-align: right;">Page 243</p> <p>1 And are you aware of any other vaccines</p> <p>2 that -- where they're alleging POTS as a result of</p> <p>3 the vaccine?</p> <p>4 A No.</p> <p>5 Q Now, some of Dr. Tomljenovic's analyses,</p> <p>6 as you talked about, go down to age six; correct?</p> <p>7 A Yes.</p> <p>8 Q And you noted that the age confounding</p> <p>9 is -- is a possibility with respect to that, because</p> <p>10 Gardasil, obviously, was used in 11- or</p> <p>11 12-year-olds, but at least, down to nine; right?</p> <p>12 A Yes.</p> <p>13 So it's not just because of 6 to 8, which</p> <p>14 I think Gardasil is not used for. It's also that</p> <p>15 there's -- e- -- even if you do 9 to 18, say,</p> <p>16 there's a certain distribution of when the vaccines</p> <p>17 are given. And it's -- it's more at the younger age</p> <p>18 versus the older age, I think.</p> <p>19 Then, there's a different age</p> <p>20 distribution in terms of the outcomes, whether it's</p> <p>21 POTS or anything else. So those distribution will</p> <p>22 not be identical.</p> <p>23 And then, of course, you have the</p> <p>24 comparison vaccines, which other vaccines, they have</p> <p>25 a different age distribution than -- than -- than</p>	<p style="text-align: right;">Page 245</p> <p>1 Q Did you --</p> <p>2 A -- or what you include.</p> <p>3 Q -- did you know that the VAERS --</p> <p>4 Dr. Kulldorff, did you know that the VAERS data can</p> <p>5 be downloaded into CSV files?</p> <p>6 A I know that the VAERS data can be</p> <p>7 downloaded.</p> <p>8 Q And into a --</p> <p>9 A Or --</p> <p>10 Q -- CSV file that can then be put into a</p> <p>11 different program, and you can sort by age; right?</p> <p>12 A I don't know exactly what -- I don't know</p> <p>13 what is the -- so -- so I don't know what is the</p> <p>14 exact nature of the data that is being downloaded.</p> <p>15 Q That's my question.</p> <p>16 A Yeah.</p> <p>17 Q You don't -- you don't know the exact</p> <p>18 nature of the data that's downloaded from VAERS to</p> <p>19 know whether you could exclude six-, seven-, and</p> <p>20 eight-year-olds; right?</p> <p>21 A I don't know.</p> <p>22 Q Okay. In any event, she didn't; right?</p> <p>23 A Correct.</p> <p>24 Q Okay. Now, her analysis also excluded</p> <p>25 COVID vaccines; right?</p>

<p style="text-align: right;">Page 246</p> <p>1 A Yes.</p> <p>2 Q You're aware that -- again, based on your 3 experience -- that people have reported the 4 development of POTS and POI after COVID vaccines; 5 correct?</p> <p>6 A I know there has been the reports of -- 7 there has been a fair amount of discussion about 8 COVID vaccines and various menstrual issues --</p> <p>9 Q Now --</p> <p>10 A -- that could be related to, maybe, POI. 11 POTS, I really don't know one way or the 12 other.</p> <p>13 Q Now, let's talk about the Chao study, 14 2012 --</p> <p>15 A Okay.</p> <p>16 Q -- for a minute; okay?</p> <p>17 You obviously reviewed that study in 18 connection with your expert report?</p> <p>19 A Yes, I did.</p> <p>20 Q First off, Chao 2012 doesn't have an end 21 point in it related to POTS or POI; correct?</p> <p>22 A That is correct.</p> <p>23 Q Did you know that that study is known as 24 protocol 031?</p> <p>25 A I -- I haven't heard that number.</p>	<p style="text-align: right;">Page 248</p> <p>1 post-marketing study that evaluated whether Gardasil 2 was associated with the development of autoimmune 3 disease; correct?</p> <p>4 A Correct.</p> <p>5 Q Can you confirm that there are now dozens 6 of studies that have looked at whether Gardasil is 7 associated with the development of autoimmune 8 disease?</p> <p>9 A Yes.</p> <p>10 Q Some, but not all of those studies you 11 actually cited in your Yih 2018 and 2021 12 publications; true?</p> <p>13 A Probably true.</p> <p>14 Q Did you, in your research for this case, 15 review any public analyses by the FDA or its medical 16 officers related to the development of autoimmune 17 disease in Gardasil clinical trials?</p> <p>18 A You mean, scientific papers by FDA 19 personnel? Or...</p> <p>20 Q Ei- -- either scientific papers by FDA 21 personnel, analyses by medical officers that are 22 employed by the FDA, or any other statements by the 23 FDA.</p> <p>24 I'm trying not to be restrictive here.</p> <p>25 A Autoimmune diseases specifically?</p>
<p style="text-align: right;">Page 247</p> <p>1 Q You did not review any internal documents 2 from Merck or anyone else related to study 031 or 3 the Chao study; right?</p> <p>4 A So there were the depositions that 5 discussed the Chao study. And I read, not the whole 6 deposition, but I read parts of the depositions.</p> <p>7 Q Did you go back and review all the 8 exhibits that were discussed in those?</p> <p>9 A No.</p> <p>10 Q Okay. Do you know whether or not 11 there -- well, withdrawn.</p> <p>12 Do you know that there's, like, a 13 thousand-page clinical study report that relates to 14 031?</p> <p>15 A No.</p> <p>16 Q Did you know that there was an interim 17 study report that the FDA requested that was 18 provided to them?</p> <p>19 A I've only read the final published paper.</p> <p>20 Q Again, in fairness, you have not reviewed 21 all the information that was provided by Kaiser or 22 Merck to the FDA related to 031 or the Chao study; 23 right?</p> <p>24 A Correct.</p> <p>25 Q Now, the Chao 2012 paper was just one</p>	<p style="text-align: right;">Page 249</p> <p>1 Q Yes, sir.</p> <p>2 A And you said "FDA," not CDC?</p> <p>3 Q That's right.</p> <p>4 A I -- I -- I may have. I think some of 5 the -- I don't remember exactly which one had the 6 FDA authors versus -- versus, for example, CDC 7 authors.</p> <p>8 Q What's in your mind right now?</p> <p>9 A Well, the spontaneous report by the -- 10 let me see if -- I think that we looked at that 11 paper. No?</p> <p>12 Or did I cite it here?</p> <p>13 Maybe I didn't cite that one in my paper.</p> <p>14 But...</p> <p>15 Well, the Shimabukuro paper on -- data 16 mining paper on spontaneous reports, that looked at 17 some autoimmune diseases, for example.</p> <p>18 Q Okay.</p> <p>19 A And I think there were some FDA authors 20 on that paper, but I would have to look up to make 21 sure.</p> <p>22 Q Okay. Any other --</p> <p>23 A I'm -- I -- I'm sorry I can't keep track 24 of -- of -- you probably keep track of all these 25 papers better than I do. So...</p>

<p style="text-align: right;">Page 250</p> <p>1 Q I understand. 2 Any other paper that's in your mind right 3 now when I ask that question? 4 A There might -- 5 Q Are there -- 6 A -- have been other ones. Yeah. 7 Q Okay. Do you -- did you ever see the 8 original protocol for study 031, the Chao study? 9 A No. I haven't read that. 10 Q Do you understand that the Kaiser 11 entities actually performed the data analysis for 12 the Chao study? 13 A Yeah. I think it was Southern California 14 who did the analysis. 15 Q Did you know that the 16 autoimmune-vaccinated versus -unvaccinated 17 comparison analysis was actually requested by the 18 Safety Review Committee for that publication? 19 A Can you repeat that question? 20 Q Sure. 21 Did you know that there was a Safety 22 Review Committee in Chao? 23 A Yes. 24 Q Okay. Did you know that that -- well, 25 withdrawn.</p>	<p style="text-align: right;">Page 252</p> <p>1 Q Well, they certainly interpreted -- 2 interpreted their own analysis. 3 But in terms of whether there was a 4 signal for autoimmune disease, did you know that the 5 SRC actually weighed in on that? 6 A You mean, in the paper? Or -- 7 Q Yes, sir. 8 In the paper or any other time. 9 A I just thought that -- well, I don't -- I 10 don't know if they weighed in on that or not. 11 I just figured that it's the authors of 12 the paper are responsible for whatever the 13 conclusions or interpretation they do. 14 Q Did you also understand that the SRC, the 15 Safety Review Committee, came to the decision that 16 the autoimmune analysis did not suggest a signal 17 that Gardasil was associated with the development of 18 autoimmune disease? 19 A I'm not aware what the opinion they had 20 on that. 21 Q Now, as I read your report, you com -- 22 you claim that the -- withdrawn. 23 As I read your expert report, you claim 24 that there's no useful information that can be 25 derived from the main analysis or sensitivity</p>
<p style="text-align: right;">Page 251</p> <p>1 Do you know who was on the Safety Review 2 Committee? 3 A No. 4 Q Do you know whether or not that they were 5 experts in vaccine safety analysis? 6 A I don't know who they were, so I don't 7 know what their expertise was. 8 Q Do you know if they were -- withdrawn. 9 Do you know if this SRC members were 10 employees of Merck? 11 A I assume that was -- they were not, but I 12 can't promise that. 13 So since I'm under oath, I have to say I 14 don't know. 15 Q Do you know that the comparison between 16 unvaccinated versus vaccinated was actually 17 requested by the SRC, the Safety Review Committee? 18 A I know that there was some request 19 specific. I forgot exactly the specifics of that 20 request. 21 Q Did you understand, based on your review 22 of Chao, that the Safety Review Committee was 23 responsible for interpretation of the safety data? 24 A I thought the authors were responsible 25 for the interpretation of the analysis.</p>	<p style="text-align: right;">Page 253</p> <p>1 analysis number two; correct? 2 A Sensitivity analysis number two, which 3 one was that? 4 That was -- 5 Q Sensitivity analysis two was based on the 6 original ICD-9 codes. It was not all versus all. 7 There was imputation involved in 8 sensitivity analysis number two. 9 Tell you what -- 10 A Did you have the -- I -- I'm just going 11 to -- 12 Q Oh -- 13 A Do you have the -- I think I have -- 14 you've already given me that. But -- 15 Q Oh, I've already marked it. 16 MR. BAUM: Yeah. 17 BY MR. TOMASELLI: 18 Q That's right. 19 A It's somewhere in this -- 20 Q Toward the bottom, probably. 21 A Here it is. 22 MR. BAUM: It's -- it's nine, if 23 that helps. 24 THE WITNESS: Yeah. Correct. 25 A So I -- I -- I think that you're</p>

<p style="text-align: right;">Page 254</p> <p>1 correct -- no useful information can be obtained 2 either from the main comparison or sensitivity 3 analysis number two.</p> <p>4 BY MR. TOMASELLI:</p> <p>5 Q With respect to sensitivity analysis 6 number one, that was all identified cases versus all 7 identified cases -- right? -- with -- with no --</p> <p>8 A No medical --</p> <p>9 Q -- analysis --</p> <p>10 A -- struc- -- no medical structure, too.</p> <p>11 Q That's right. Okay.</p> <p>12 We agree often that?</p> <p>13 A Yes.</p> <p>14 Q All right. And within Kaiser Southern 15 California, in terms of the populations, there were 16 over 500,000 people, total, in the vaccinated versus 17 unvaccinated group; fair?</p> <p>18 A If you say so. I can check it, but I 19 trust you.</p> <p>20 Q If you look at the bottom of page 196, 21 the bottom right, can you confirm that the Kaiser 22 Permanente Southern California population that 23 sensitivity analysis one drew from was over 500,000 24 people?</p> <p>25 A Yes. It's five hundred six -- 561,000</p>	<p style="text-align: right;">Page 256</p> <p>1 given in the context of an autoimmune disease; 2 right?</p> <p>3 A If you say so.</p> <p>4 Q Yeah. Okay. In terms of the vaccinated 5 girls, they were getting Gardasil; correct?</p> <p>6 A Yes. I believe --</p> <p>7 Q And --</p> <p>8 A -- so.</p> <p>9 Q -- and at the time of -- of this study, 10 Gardasil was recommended in three doses; correct?</p> <p>11 A That is my understanding.</p> <p>12 Q So at time point one --</p> <p>13 A At -- at --</p> <p>14 Q -- and then --</p> <p>15 A -- some -- at --</p> <p>16 Q -- in --</p> <p>17 A -- some point, it went down to two doses. 18 But I forget exactly when that was.</p> <p>19 Q It wasn't -- it wasn't at -- at this 20 time; right?</p> <p>21 A Yup. I -- I forgot what it was. So...</p> <p>22 Q In any event, whether it's two or three 23 doses, when the girls went to their doctor with -- 24 to get a Gardasil vaccination, obviously, they went 25 to their doctor; right?</p>
<p style="text-align: right;">Page 255</p> <p>1 person-years.</p> <p>2 So that's necessari- -- that necessarily 3 the -- it's not the same as persons.</p> <p>4 Q Well, if you look at just the -- the 5 statement, it says, At KPSC, there were 117,000 6 women with 87,000 accrued person-years and 412,000 7 eligible --</p> <p>8 A Unvaccinated.</p> <p>9 Q -- unvaccinated women --</p> <p>10 A Yeah. Okay. So there would be at 11 least -- so that's 412 plus 117. That's more than 12 500. So there would be more than 500 people in the 13 study. Correct.</p> <p>14 Q 500,000 people --</p> <p>15 A Yeah.</p> <p>16 Q -- in the --</p> <p>17 A Yeah.</p> <p>18 Q -- study?</p> <p>19 What I said was correct?</p> <p>20 A Correct. Yeah.</p> <p>21 Q All right. And my understanding is that 22 potential autoimmune cases were identified in three 23 ways; one based on diagnosis codes, another based on 24 abnormal laboratory values, and another based on 25 pharmacy prescriptions that were given that might be</p>	<p style="text-align: right;">Page 257</p> <p>1 A I hope so.</p> <p>2 Q Okay. And the unvaccinated girls did not 3 necessarily go to their doctor to get a vaccination; 4 right?</p> <p>5 A They might have gone for some other 6 reasons. But they certainly didn't go there for 7 the -- for the Gardasil vaccination.</p> <p>8 Q In terms of the Gardasil vaccination, 9 it's expected that they would be there two or three 10 times visiting their doctor over an unvaccinated 11 person that wasn't getting the Gardasil; correct?</p> <p>12 A Well, often, a vaccine is given out at 13 the -- the routine annual visit.</p> <p>14 So you would expect that the first dose 15 is typically given on the -- on the annual visit, 16 whenever that is. And then, they might schedule 17 extra visits for the second dose.</p> <p>18 Q And the third dose?</p> <p>19 A Yeah.</p> <p>20 Q Do you agree that the Chao paper was 21 peer-reviewed and published?</p> <p>22 A It was.</p> <p>23 Q Do you agree that the authors -- I mean, 24 you mentioned this earlier -- that the authors of 25 the Chao paper concluded that their own analysis did</p>

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<p style="text-align: right;">Page 258</p> <p>1 not show a significant association between Gardasil 2 and autoimmune disease?</p> <p>3 A That's what this says. Yes.</p> <p>4 Q And if you look at the last -- the last 5 sentence of the results on the first page --</p> <p>6 A In the abstract?</p> <p>7 Q Yes, sir.</p> <p>8 A Okay.</p> <p>9 Q Do you see where it says, "The SRC and 10 the investigators identified no autoimmune safety 11 concerns in this study"?</p> <p>12 A Yes.</p> <p>13 Q Do you see that?</p> <p>14 A Yeah.</p> <p>15 Q So we can agree both the authors and the 16 people on the SRC, at least, did not have any safety 17 concerns for an autoimmune disease as reported in 18 the Chao paper?</p> <p>19 A So they didn't identify anything; 20 correct.</p> <p>21 Q Okay.</p> <p>22 A And they are speaking 'cause -- not only 23 for themselves, but also for the SRC.</p> <p>24 MS. VALOFF: Counsel, this is Jo 25 Lynn Valoff. I am an attorney for</p>	<p style="text-align: right;">Page 260</p> <p>1 you Exhibit No. 33, which is a page from the FDA's 2 website entitled "FDA Information on Gardasil -- 3 Presence of DNA Fragments Expected, No Safety Risk."</p> <p>4 Do you see that?</p> <p>5 A Yes.</p> <p>6 Q Have you seen this before?</p> <p>7 A Not recently.</p> <p>8 But this is an old document, so I don't 9 have any recollection of it.</p> <p>10 Q Is this something that if you saw it, it 11 would have been prior to the -- the publications 12 that we've been talking about earlier today?</p> <p>13 A It would have been, maybe, when it came 14 out. But I don't have a recollection of it --</p> <p>15 Q Okay.</p> <p>16 A -- seeing it.</p> <p>17 Q Do you see the last bullet on the first 18 page?</p> <p>19 It -- it says, "As it does with all 20 vaccines..."</p> <p>21 A Yes.</p> <p>22 Q Do you see that?</p> <p>23 It -- it says, "As it does with all 24 vaccines, FDA continues to monitor the safety of 25 Gardasil. For example, FDA recently evaluated the</p>
<p style="text-align: right;">Page 259</p> <p>1 Kaiser. 2 And I just want to correct the 3 assumption that there were 500,000 people 4 in the study.</p> <p>5 Your reference to the bottom of page 6 196, if you look on the left side at the 7 bottom, it says, "Amongst the [hundred 8 eighty-nine six hundred twenty-nine] 9 [sic] women in the autoimmune 10 surveillance..."</p> <p>11 So I -- I -- I don't think it was 12 500,000. I do agree with your prior 13 reference that there was over 500,000 14 accrued person-years.</p> <p>15 But there -- I do not believe there 16 were over 500,000 people in the study, 17 based on the reference at the bottom of 18 page 196 in the left column.</p> <p>19 (Whereupon, Exhibit MK 33, Document 20 Entitled "FDA Information on Gardasil 21 -- Presence of DNA Fragments 22 Expected, No Safety Risk," was marked 23 for identification.)</p> <p>24 BY MR. TOMASELLI: 25 Q All right. Dr. Kulldorff, I'm handing</p>	<p style="text-align: right;">Page 261</p> <p>1 results of a postmarketing [sic] study, which 2 included [a hundred and eighty-nine thousand six 3 hundred and twenty-nine females aged] [sic] 9 to 26 4 [years] [sic], 50% [sic] of whom were 9 to 15 of age 5 to assess the risk [of new onset] [sic] of 6 autoimmune diseases after vaccination with [sic] 7 Gardasil."</p> <p>8 Do you see that?</p> <p>9 A Yes.</p> <p>10 Q And the FDA paper goes on and says, 11 "Examples of these types of diseases include 12 juvenile rheumatoid arthritis, lupus, multiple 13 sclerosis, etc."</p> <p>14 Do you see that?</p> <p>15 A Yeah.</p> <p>16 Q And then, the FDA says, "The results of 17 this study showed that there is no elevated risk for 18 on- -- "for onset of new autoimmune disease 19 associated with the use of Gardasil."</p> <p>20 Do you see that?</p> <p>21 A Yeah.</p> <p>22 Q And then, on the back, it says in a 23 bullet, "FDA also continually reviews all reports of 24 the [VAERS] System after vaccination with Gardasil, 25 and there is no evidence of [an] [sic] unusual</p>

<p style="text-align: right;">Page 262</p> <p>1 clinical patterns or high reporting rates of adverse 2 events, including autoimmune diseases."</p> <p>3 Do you see that?</p> <p>4 A Yes.</p> <p>5 Q And then, it says, "One of FDA's highest 6 priorities is the protection of public health 7 through safe and effective vaccines. As it does 8 with all vaccines, FDA will continue to monitor the 9 safety of Gardasil."</p> <p>10 Do you see that?</p> <p>11 A Yes.</p> <p>12 Q Is it true that one of the FDA's -- in 13 your working with people that are employed there, is 14 it true that one of the FDA's highest priorities is 15 the protection of public health?</p> <p>16 A It should be.</p> <p>17 Q And is it true that they continually 18 monitor the safety and efficacy of vaccines?</p> <p>19 A They continually monitor the safety of 20 all vaccines.</p> <p>21 Q Does that include Gardasil?</p> <p>22 A Yes.</p> <p>23 Whether they con- -- they -- they do 24 monitor the efficacy of -- of at least some 25 vaccines. I don't know if they -- they continuously</p>	<p style="text-align: right;">Page 264</p> <p>1 Q All right. And this is the summary 2 report of the ACIP meeting from -- from 2015; right?</p> <p>3 A I think it's the summary report to the 4 ACIP meeting.</p> <p>5 Q Okay. And on page 70, the third 6 paragraph, do you see that it says, "There have also 7 been concerns for potential associations with 8 autoimmune and neurologic disease following 9 Gardasil."</p> <p>10 Do you see that?</p> <p>11 A Yes.</p> <p>12 Q And then it says, "No evidence for a 13 causal association has been observed between 14 Gardasil and autoimmune and neurologic conditions in 15 four large epidemiologic studies."</p> <p>16 Do you see that?</p> <p>17 A Yes.</p> <p>18 Q One of the studies -- one of the studies 19 that they cite is Chao; correct?</p> <p>20 A Yes.</p> <p>21 Q And the other three studies that they 22 cite at this time are Arnhem Dahlström, 23 Grimaldi-Bensouda, and Scheller; correct?</p> <p>24 A And Scheller, yeah, uh-huh. Yup.</p> <p>25 Q And, again, Dr. Sukumaran, he is -- he's</p>
<p style="text-align: right;">Page 263</p> <p>1 monitor the safe -- the efficacy of vaccines. I 2 doubt it.</p> <p>3 Q Can you turn back to Exhibit 18, which is 4 Sukumaran 2015?</p> <p>5 A You said 18?</p> <p>6 Q Yes, 18. Sorry.</p> <p>7 Did I say something else?</p> <p>8 A No, I was just --</p> <p>9 Q I think it was 18? It was the one with 10 the CDC picture on the front.</p> <p>11 MR. BAUM: Looks like that.</p> <p>12 BY MR. TOMASELLI:</p> <p>13 Q There you go.</p> <p>14 A Yeah.</p> <p>15 Q That's it. Sorry to make you flip 16 through all these. No other way to do it.</p> <p>17 Okay. Withdrawn.</p> <p>18 Do you have Exhibit 18 in front of you, 19 sir?</p> <p>20 A Yes.</p> <p>21 Q And we looked at page 69 of this ACIP 22 publication previously and it's got "Update on HPV 23 Vaccine Safety by Dr. Sukumaran."</p> <p>24 Right?</p> <p>25 A Yeah.</p>	<p style="text-align: right;">Page 265</p> <p>1 with the -- the U.S. CDC in their immunization 2 safety office; right?</p> <p>3 A Yes.</p> <p>4 Q Okay. The -- well -- withdrawn.</p> <p>5 In your expert report at page 24, at the 6 bottom you have a section called "Safety of the 7 Gardasil" --</p> <p>8 A Yup.</p> <p>9 Q -- "Vaccine."</p> <p>10 Do you see that?</p> <p>11 A Yeah.</p> <p>12 Q And the first sentence there, you say, 13 "The Chao paper contributed nothing regarding 14 potential adverse reactions to the Gardasil vaccine 15 in either direction"?</p> <p>16 A Correct.</p> <p>17 Q And what do you mean by "in either 18 direction"?</p> <p>19 A It doesn't contribute anything in terms 20 of saying that there is a problem or that there is 21 not a problem.</p> <p>22 If you have a study that is flawed, 23 fundamentally flawed, it provides no information and 24 you cannot use it, neither to claim that there is a 25 relationship or that there is not.</p>

<p style="text-align: right;">Page 266</p> <p>1 You have to sort of just put it aside and 2 say, well, this is useless --</p> <p>3 Q Okay.</p> <p>4 A -- and then focus on other studies that 5 can help you build this jigsaw puzzle with a piece 6 here and a piece there and a piece there.</p> <p>7 But the shell paper is useless to build 8 that jigsaw puzzle to find out the safety profile of 9 the Gardasil vaccine.</p> <p>10 Q And so I just want to make sure we are 11 clear too that it's not your opinion anywhere that 12 the Chao paper actually shows evidence of an 13 increased risk?</p> <p>14 A It shows evidence of nothing.</p> <p>15 Q Okay.</p> <p>16 A No evidence of any kind.</p> <p>17 Q In your -- in your report in this case, I 18 think we've discussed Merck's response with respect 19 to the Article 20 procedure, as well as the Chao 20 paper; correct?</p> <p>21 A Say that again?</p> <p>22 Q Yeah, so --</p> <p>23 A I was --</p> <p>24 Q -- with respect to your expert report in 25 this case in terms of the things that -- that Merck</p>	<p style="text-align: right;">Page 268</p> <p>1 I -- when I do my literature search, I 2 was not searching by authors, I was searching about 3 topic that was papers relevant in terms of the topic 4 of the paper.</p> <p>5 Q Do you know if, for example, that first 6 Grimaldi-Bensouda 2014 paper was sponsored by 7 Merck --</p> <p>8 A I don't know --</p> <p>9 Q -- or a post marketing commitment?</p> <p>10 A -- I don't know if it was or not.</p> <p>11 Q Don't know?</p> <p>12 Was the Klein 2012 paper sponsored by 13 Merck?</p> <p>14 A Is that the paper that looked at short 15 reviews?</p> <p>16 Q Hiccup codes, yup.</p> <p>17 A I'm not hundred percent sure. It might 18 have been, but I'm not a hundred percent sure.</p> <p>19 Q In terms of other analyses -- post 20 marketing analyses sponsored by Merck related to 21 autoimmune conditions, you have -- you have not 22 undertaken to find those and analyze those; right?</p> <p>23 A I have not done any attempt to find 24 papers specifically authored by Merck or sponsored 25 by Merck.</p>
<p style="text-align: right;">Page 267</p> <p>1 had a -- had -- well, withdrawn.</p> <p>2 You discussed the Chao paper in your 3 expert report?</p> <p>4 A Yes.</p> <p>5 Q Correct?</p> <p>6 A Yup.</p> <p>7 Q You also discussed Merck's response to 8 the Article 20 questions from the PRAC?</p> <p>9 A Yeah.</p> <p>10 Q Correct?</p> <p>11 A Yeah.</p> <p>12 Q Did you undertake an analysis to see if 13 Merck sponsored or participated in other studies 14 pertaining to the safety of Gardasil after 15 marketing?</p> <p>16 A You mean that was not mentioned in their 17 report to the EMA?</p> <p>18 Q Whether mentioned to the report in the 19 EMA or otherwise, did you yourself -- you, 20 Dr. Kulldorff, in -- in working on this litigation 21 say, you know what, I looked at two things, I wonder 22 if there's other things?</p> <p>23 Did you ever think that to yourself?</p> <p>24 A So I never did any search for looking at 25 particular studies that was authored by Merck.</p>	<p style="text-align: right;">Page 269</p> <p>1 Q For example, if there was a paper out 2 there related to autoimmune disease from a first 3 author of Hanson (phonetic), that's not something 4 that you've looked at?</p> <p>5 A I don't think I've looked at the Hanson 6 paper.</p> <p>7 Q Okay. And you haven't looked at a paper 8 from Seeger (phonetic) and others related to 9 potential development of autoimmune disease; right?</p> <p>10 A I don't think I read that paper, at least 11 not recently.</p> <p>12 MR. TOMASELLI: I'm going to mark as 13 Exhibit 34 -- is that right? Is that 14 right?</p> <p>15 MR. BAUM: I think so.</p> <p>16 MR. WEBER: Yes, 34.</p> <p>17 MR. BAUM: Yeah.</p> <p>18 (Whereupon, Exhibit MK 34, Fukushima 19 Paper, was marked for 20 identification.)</p> <p>21 BY MR. TOMASELLI:</p> <p>22 Q I'm going to mark as Exhibit 34 a paper 23 by Fukushima, F-u-k-u- --</p> <p>24 A Yes.</p> <p>25 Q -- s-h-i-m-a, and 11 other Japanese</p>

<p style="text-align: right;">Page 270</p> <p>1 authors; correct?</p> <p>2 A This is by Fukushima from Japan and --</p> <p>3 one, two, three, four, five, six -- yes, 11 others.</p> <p>4 Q And this is an analysis that you --</p> <p>5 withdrawn.</p> <p>6 This is a paper that you cited in your</p> <p>7 written expert report; correct?</p> <p>8 A I did cite it, yes.</p> <p>9 Q This -- this paper was a survey study in</p> <p>10 Japan to determine if girls who were unvaccinated</p> <p>11 also reported diverse symptoms to their doctors;</p> <p>12 correct?</p> <p>13 A That was a major thing of this to find</p> <p>14 out if there were people not exposed to the vaccine</p> <p>15 who also -- so basically if this condition was also</p> <p>16 present in unvaccinated people -- or HPV</p> <p>17 unvaccinated women.</p> <p>18 Q And in your expert report, you very</p> <p>19 simply compared the prevalence of symptoms that</p> <p>20 occurred in girls after vaccination versus</p> <p>21 unvaccinated; true?</p> <p>22 A Well, I think that there was Fukushima</p> <p>23 who compared that.</p> <p>24 Q Well, actually, you're the one who</p> <p>25 compared them in your expert report; right?</p>	<p style="text-align: right;">Page 272</p> <p>1 Q It says, "In addition to the prevalence</p> <p>2 of diverse symptoms among girls without a history of</p> <p>3 HPV vaccination, group A, we estimated the</p> <p>4 prevalence among vaccinated girls whose symptoms</p> <p>5 occurred after vaccination, group C."</p> <p>6 Do you see that?</p> <p>7 A Yes.</p> <p>8 Q And then the authors say, "However, these</p> <p>9 estimates cannot directly" -- sorry, withdrawn.</p> <p>10 The authors then go on to state,</p> <p>11 "However, these estimates cannot be directly</p> <p>12 compared between groups because suspension of the</p> <p>13 proactive recommendation for HPV vaccination in</p> <p>14 Japan led to a smaller vaccinated population among</p> <p>15 girls aged 12 to 14 years, table five."</p> <p>16 Do you see that?</p> <p>17 A Yes.</p> <p>18 Q Then if you keep going down in that</p> <p>19 column, there's a last paragraph on the page,</p> <p>20 left-hand side, do you see, that says, "There are</p> <p>21 other reasons why"?</p> <p>22 Do you see that?</p> <p>23 A Uh-huh.</p> <p>24 Q The Fukushima authors on -- continuing on</p> <p>25 page 40, say, "There are other reasons why we cannot</p>
<p style="text-align: right;">Page 271</p> <p>1 A I think it's in figure two.</p> <p>2 Q All right. Did -- now figure two shows</p> <p>3 the prevalence of symptoms, but there's no actual</p> <p>4 statistical comparison of them; correct?</p> <p>5 A Yeah, they did not -- Fukushima didn't do</p> <p>6 any sort of proper analysis of, I think, anything in</p> <p>7 this paper.</p> <p>8 Q Well, Fukushima, in fairness, said that</p> <p>9 you should not compare the prevalence of -- of</p> <p>10 symptoms between vaccinated and unvaccinated; true?</p> <p>11 A I don't remember --</p> <p>12 Q Okay.</p> <p>13 A -- if they -- what they -- how they</p> <p>14 phrased that.</p> <p>15 Q Okay. So let's go to page 40 and see</p> <p>16 if -- see if we can look at that?</p> <p>17 A Just give me a few seconds.</p> <p>18 Q Yeah, sure.</p> <p>19 A Okay.</p> <p>20 Q Do you see there's a discussion on</p> <p>21 page 40?</p> <p>22 A Yes.</p> <p>23 Q And three paragraphs down, do you see</p> <p>24 there's a statement that says, "In addition"?</p> <p>25 A Yes.</p>	<p style="text-align: right;">Page 273</p> <p>1 compare prevalence between unvaccinated and</p> <p>2 vaccinated girls."</p> <p>3 Do you see that?</p> <p>4 A Uh-huh. Yes.</p> <p>5 Q On the right-side column on -- staying on</p> <p>6 page 40, toward the bottom, second to last</p> <p>7 paragraph, do you see it says, "Orthostatic</p> <p>8 dysregulation"?</p> <p>9 A Yes.</p> <p>10 Q Then the next sentence says, "Our</p> <p>11 findings were in line with the fact that POTS has</p> <p>12 been infrequently evaluated as a possible adverse</p> <p>13 event following HPV vaccination, 37 to 41, although</p> <p>14 the majority of the reports found no significant</p> <p>15 safety concern or supportive evidence for a causal</p> <p>16 relationship"?</p> <p>17 A No, it said "frequently."</p> <p>18 You meant -- you read it as</p> <p>19 "infrequently."</p> <p>20 Q Oh, I'm sorry.</p> <p>21 A It says "infrequently."</p> <p>22 Q That's my bad. So withdrawn. I'll --</p> <p>23 let's start again.</p> <p>24 Do you see on page 40 where the Fukushima</p> <p>25 authors state, "Our findings were in line with the</p>

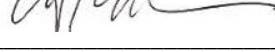
<p style="text-align: right;">Page 274</p> <p>1 fact that POTS has been frequently evaluated as a 2 possible adverse event following HPV vaccination, 37 3 to 41, although the majority of reports found no 4 significant safety concern or supportive evidence 5 for a causal relationship."</p> <p>6 Do you see that?</p> <p>7 A Yes.</p> <p>8 Q And in terms of the footnotes 37 through 9 41, they support their statement with a variety of 10 cites, and 37 is the World Health Organization; 11 correct?</p> <p>12 A Yes.</p> <p>13 Q Thirty-eight is the Arana study?</p> <p>14 A Yes.</p> <p>15 Q Thirty-nine is the Philips 2018 study?</p> <p>16 A Yes.</p> <p>17 Q Number 40 is Ward 2019; correct?</p> <p>18 A Yes.</p> <p>19 Q Forty-one is Barboi, B-a-r-b-o-i, from 20 2020; correct?</p> <p>21 A Correct.</p> <p>22 Q If you turn to the first page of the 23 article in the abstract -- well, withdrawn.</p> <p>24 First of all, just so we are clear, 25 the -- the Fukushima authors stated in their</p>	<p style="text-align: right;">Page 276</p> <p>1 of them, then there's not much of a difference. If 2 you look at many of them, there is a bigger 3 difference.</p> <p>4 So in -- in a sense, I was comparing not 5 so much the vaccinated and unvaccinated, but I was 6 comparing the difference here to the difference here 7 at fewer doses versus the difference at many doses, 8 which is much higher in terms of the -- the -- the 9 magnitude of the number of times, 40 percent versus 10 three times.</p> <p>11 MR. BAUM: And, Doctor, do you mean 12 doses or -- or symptoms?</p> <p>13 THE WITNESS: These are symptoms.</p> <p>14 A So my point is that if you then do a 15 study of POTS, and you say they have one or two 16 symptoms of POTS, you might not see a difference 17 because it might potentially, and this is just sort 18 of a -- a descriptive things of POTS.</p> <p>19 But if you then want to do a formal 20 study, which Fukushima doesn't do, maybe you need to 21 focus it on those who have many symptoms because 22 that is actually where you see the biggest relative 23 difference here in the Fukushima.</p> <p>24 So that would be a sort of one plausible 25 things to moving forward to sort of focus in on</p>
<p style="text-align: right;">Page 275</p> <p>1 publication that you shouldn't compare prevalence 2 between vaccinated and unvaccinated; correct? We 3 just went over that?</p> <p>4 A They mention something of that.</p> <p>5 Q Yeah. And even though the Fukushima 6 authors say in their paper that you shouldn't 7 compare prevalence, you actually did compare the 8 prevalence in your written expert report; correct?</p> <p>9 A I looked at figure two where they compare 10 the prevalence --</p> <p>11 Q Right?</p> <p>12 A -- in the vaccinated and unvaccinated and 13 I basically just used -- used that.</p> <p>14 Q Okay. But you actually ascribed 15 differences to the numbers; right?</p> <p>16 A Yeah, so I just divided their 27.8 and 17 20.2 and then I -- which is about a 40 percent 18 difference there and there's about a threefold 19 difference between 5.3 and --</p> <p>20 (Whereupon, the court reporter 21 requests clarification.)</p> <p>22 A -- threefold -- threefold difference 23 between 5.3 and 15.6 for more than ten.</p> <p>24 So my point was that these are different 25 POTS-related symptoms and if you look at only a few</p>	<p style="text-align: right;">Page 277</p> <p>1 where they found a big difference in Fukushima. 2 But, I mean, they don't do a technical, formal 3 comparison of this.</p> <p>4 And I think --</p> <p>5 BY MR. TOMASELLI:</p> <p>6 Q Let me --</p> <p>7 A Yeah.</p> <p>8 Q -- ask you this, Dr. Kulldorff: Are you 9 aware of data from Japan that did do a formal 10 analysis of multiple symptoms versus multiple 11 symptoms, did you look for that?</p> <p>12 A I have not did a literature search for 13 that, no.</p> <p>14 Q Okay. Before we get there, if you'll 15 come back to the abstract with me real quick.</p> <p>16 The conclusion of the authors states that 17 adolescent Japanese girls without HPV vaccination 18 also visited hospitals with diverse symptoms similar 19 to those following HPV vaccination; true?</p> <p>20 A Yeah, I think that was the main point of 21 the paper that they weren't sure that there were 22 girls who do -- who were not vaccinated with 23 Gardasil who also had these type of symptoms.</p> <p>24 Q Yeah.</p> <p>25 A So it's not something that is unique to</p>

<p style="text-align: right;">Page 278</p> <p>1 vaccinated girls.</p> <p>2 Q And the next sentence states, "Our</p> <p>3 findings predict the medical demands for coincident</p> <p>4 diverse symptoms, which are temporally associated</p> <p>5 with but not caused by HPV vaccination of Japanese</p> <p>6 adolescents."</p> <p>7 Do you see that?</p> <p>8 A That was also in the --</p> <p>9 Q The last --</p> <p>10 A Yes.</p> <p>11 Q -- last line of the abstract?</p> <p>12 A I see that.</p> <p>13 Q Do you see that, sir?</p> <p>14 A I see that.</p> <p>15 Q That's what the Fukushima authors</p> <p>16 concluded from their data; correct?</p> <p>17 A That was in the conclusion, yeah.</p> <p>18 Q And you said you weren't aware of studies</p> <p>19 in Japan where multiple symptoms were investigated.</p> <p>20 MR. TOMASELLI: And so I want to</p> <p>21 hand you Exhibit Number 35 --</p> <p>22 (Whereupon, Exhibit MK 35, Suzuki and</p> <p>23 Hokono Article, was marked for</p> <p>24 identification.)</p> <p>25 A Thank you.</p>	<p style="text-align: right;">Page 280</p> <p>1 Q And the authors state that, There is no</p> <p>2 significant increase in the occurrence of any of</p> <p>3 the 24 reported post-HPV vaccination symptoms was</p> <p>4 found.</p> <p>5 Do you see that?</p> <p>6 A Yes. And then it continues.</p> <p>7 Q Right.</p> <p>8 A Showing some increase for some things.</p> <p>9 Q Right. And it's -- because broken down</p> <p>10 by a lot of different things and we can look at</p> <p>11 that, but ultimately -- well, withdrawn.</p> <p>12 The conclusion, the last sentence of the</p> <p>13 abstract, states that these -- I'm sorry, the</p> <p>14 results suggest no causal association between HPV</p> <p>15 vaccines and reported symptoms; correct?</p> <p>16 A That's what it says.</p> <p>17 Q Now, in -- in the last paper, you were</p> <p>18 talking about the occurrence of one or more symptoms</p> <p>19 in girls; correct?</p> <p>20 A Correct.</p> <p>21 Q Now, if you turn to page 99, there is a</p> <p>22 little bit of text between the -- between figure two</p> <p>23 and table two; do you see that?</p> <p>24 A Yes.</p> <p>25 Q The authors state, "There was no</p>
<p style="text-align: right;">Page 279</p> <p>1 BY MR. TOMASELLI:</p> <p>2 Q -- which is an article from Suzuki and</p> <p>3 Hosono, H-o-s-o-n-o, related to the Nagoya City</p> <p>4 study.</p> <p>5 Have you seen this before?</p> <p>6 A I have not.</p> <p>7 Q Okay. If you can turn -- well, first of</p> <p>8 all, this is a study investigating the potential</p> <p>9 association between vaccine and reported symptoms in</p> <p>10 Japan; true?</p> <p>11 A Let me read the abstract at least --</p> <p>12 Q Sure.</p> <p>13 A -- before you ask questions about it.</p> <p>14 Q You bet.</p> <p>15 A Okay. I mean, I haven't read the whole</p> <p>16 paper now --</p> <p>17 Q No.</p> <p>18 A -- but I at least glanced through it.</p> <p>19 Q Fair enough.</p> <p>20 And hopefully, you know, if -- if you</p> <p>21 need to read more, that's fine. But -- withdrawn.</p> <p>22 The -- the abstract states that about</p> <p>23 30,000 girls in Nagoya City responded to this</p> <p>24 survey; right?</p> <p>25 A Correct.</p>	<p style="text-align: right;">Page 281</p> <p>1 statistically significant association between any of</p> <p>2 the 24 reported symptoms and school performance,</p> <p>3 school activities, other than studying and job</p> <p>4 hunting and employment, at" -- and then it -- then</p> <p>5 it provides a -- a few confidence intervals.</p> <p>6 Do you see where I am?</p> <p>7 A Yes.</p> <p>8 Q Okay. The next sentence is the one I</p> <p>9 want you to focus on, which states, "The odds ratios</p> <p>10 for development of one or more symptoms," and then</p> <p>11 it has a series of odds ratios, which include</p> <p>12 greater than one, greater than three, greater than</p> <p>13 four, and greater than nine, which is ten or more</p> <p>14 symptoms, and notes that there was no significant</p> <p>15 association between HPV vaccination and multiple</p> <p>16 symptoms; correct?</p> <p>17 A That's what it says.</p> <p>18 Q Right. And so if we looked at the last</p> <p>19 one, for example, this idea of greater than nine, so</p> <p>20 those girls that have ten or more symptoms, the odds</p> <p>21 ratio was .76 and actually was statistically</p> <p>22 significantly decreased in the vaccinated versus</p> <p>23 unvaccinated; correct?</p> <p>24 A That's correct.</p> <p>25 Q All right. So at least -- and I know you</p>

<p style="text-align: right;">Page 282</p> <p>1 haven't looked at this study before, but at least 2 this appears to be a study that had formal analysis 3 of multiple symptoms between vaccinated and 4 unvaccinated; correct?</p> <p>5 A Yeah. But I don't think these are the 6 same multiple symptoms because I think in the 7 Fukushima paper they look at various symptoms 8 related to POTS, while here some of them are related 9 to POTS but I don't think all of them are.</p> <p>10 Q Right. Some of them?</p> <p>11 A So I think it's a -- I mean, a loss of 12 ability to remember fundamental kanji, for example. 13 I don't know how that's related --</p> <p>14 (Whereupon, the court reporter 15 requests clarification.)</p> <p>16 MR. TOMASELLI: Kanji, k-a-n-j-i.</p> <p>17 A I don't know how that's related to POTS, 18 for example. Or --</p> <p>19 BY MR. TOMASELLI:</p> <p>20 Q Yeah, there's 24 different symptoms in 21 this paper; correct?</p> <p>22 A Yeah, so that's -- so that's very 23 different from trying to define sort of a similar 24 definition for POTS. That's -- is just not includes 25 one or two things. That could be more generally</p>	<p style="text-align: right;">Page 284</p> <p>1 dysfunction, autonomic dysfunction, and cognitive 2 impairment."</p> <p>3 Do you see that?</p> <p>4 A Uh-huh.</p> <p>5 Q And those symptoms persist at least 6 three months; right?</p> <p>7 A Uh-huh.</p> <p>8 Q All right. Is that a yes?</p> <p>9 A Yeah, I -- I see that, but I don't see 10 all the -- all the ten symptoms. That should be 11 somewhere in the paper. I forgot where that was.</p> <p>12 Q Okay. Oh, by the way, while you are on 13 Fukushima, can you turn to table E7 -- E, 14 table seven?</p> <p>15 A What page is that on?</p> <p>16 Q Page ten of the supplemental materials.</p> <p>17 A Okay. Thank you.</p> <p>18 Yup.</p> <p>19 Q Do you see how they -- in the table, 20 there's five rows, no consideration, less than or 21 equal to a year, less than or equal to six months; 22 do you see that, sir?</p> <p>23 A Yes.</p> <p>24 Q The -- if you don't consider when 25 symptoms occurred at all in connection with</p>
<p style="text-align: right;">Page 283</p> <p>1 caused by a lot of -- sort of commonly caused by a 2 lot of things.</p> <p>3 Q All right.</p> <p>4 A So I think these -- I mean, these 24 5 symptoms are not specifically POTS-related. So I 6 don't think that's very much related to what 7 Fukushima is trying to do.</p> <p>8 Q The symptoms do include, Dr. Kulldorff, 9 things like headache, fatigue, poor endurance, 10 difficulty concentrating, dizziness, difficulty 11 falling asleep.</p> <p>12 Do you see all those?</p> <p>13 A Yeah. So what are the lists for the 14 inclusions in the --</p> <p>15 Q Yeah, if you look at --</p> <p>16 A -- Fukushima -- Fukushima.</p> <p>17 Q Table two -- table two, for example.</p> <p>18 A No, but I was thinking of the Fukushima.</p> <p>19 They also have a list of the various symptoms 20 somewhere.</p> <p>21 Q So if you look at the abstract of 22 Fukushima, sir, in the methods, it says that, 23 "Eligible patients had to satisfy four criteria: An 24 age criteria and at least one of four symptoms or 25 disorders: pain, sensory dysfunction, motor</p>	<p style="text-align: right;">Page 285</p> <p>1 vaccination, the period prevalence was 27.8; 2 correct?</p> <p>3 A Yes.</p> <p>4 Q That -- that -- that actually matches up 5 with your figure two, 27.8?</p> <p>6 A Yes.</p> <p>7 Q And if you only, according to table E7, 8 look at symptoms that occurred within a year, first 9 symptom within a year of vaccination, that period 10 prevalence is 17.5?</p> <p>11 A Right.</p> <p>12 Q Correct?</p> <p>13 A Yeah.</p> <p>14 Q And that number is actually lower than 15 the never vaccinated; correct? 17.5 is --</p> <p>16 A Well, you have to --</p> <p>17 Q -- lower?</p> <p>18 A -- compare apples to apples here.</p> <p>19 Q Well, the --</p> <p>20 A You can't compare -- you have to compare 21 apples to apples, so --</p> <p>22 Q Okay. All right. You can set that one 23 aside.</p> <p>24 If you can come back to your --</p> <p>25 A Yeah.</p>

<p style="text-align: right;">Page 286</p> <p>1 Q -- materials considered list, which is 2 Exhibit 2 --</p> <p>3 THE WITNESS: If I can have break 4 within --</p> <p>5 MR. TOMASELLI: Oh, yeah.</p> <p>6 THE WITNESS: -- within ten minutes 7 or so. I don't want a break necessarily 8 right now, but at some point within the 9 next ten, 15 minutes.</p> <p>10 MR. TOMASELLI: Let's do a break 11 right now.</p> <p>12 THE WITNESS: Okay.</p> <p>13 THE VIDEOGRAPHER: The time is 14 3:34 p.m. and we are off the record. 15 (Whereupon, there was a recess taken 16 from 3:34 p.m. to 3:49 p.m.)</p> <p>17 THE VIDEOGRAPHER: The time is 18 3:49 p.m. and we are on the record.</p> <p>19 BY MR. TOMASELLI:</p> <p>20 Q Dr. Kulldorff, are you ready to proceed?</p> <p>21 A Yes. (Whereupon, Exhibit MK 36, Invoice, 22 was marked for identification.)</p> <p>24 BY MR. TOMASELLI:</p> <p>25 Q All right. I'm going to mark as</p>	<p style="text-align: right;">Page 288</p> <p>1 "HPV Vaccine Safety and Effectiveness Data." 2 Do you see that?</p> <p>3 A I see that.</p> <p>4 Q Is that the CDC's website?</p> <p>5 A I have no idea --</p> <p>6 Q All right.</p> <p>7 A -- what it is.</p> <p>8 Q All right. Number -- number 48, it's a 9 article related to adverse events with bivalent HPV 10 vaccination in Finland; do you see that?</p> <p>11 A The 49? Or which one?</p> <p>12 Q Forty-eight, sir?</p> <p>13 A Forty-eight? Yeah, I see that.</p> <p>14 Q And 49 is the supplement for that 15 article; is that right?</p> <p>16 A Yeah. So 48, that's the Skufca article.</p> <p>17 Q Yeah.</p> <p>18 A Is it? Is it?</p> <p>19 Q Yes.</p> <p>20 A Okay, yeah.</p> <p>21 Q And 51 is the Thompson article; right?</p> <p>22 A I'm not sure.</p> <p>23 Q Okay. Some other -- well, do you know if 24 you cited the Yih 2015 -- 2016 article in this?</p> <p>25 A The Katherine E. or the --</p>
<p style="text-align: right;">Page 287</p> <p>1 Exhibit 36 the invoice that we were sent last night. 2 Is that a true and accurate copy of the 3 invoice that we talked about earlier today? 4 A Yes, it is. 5 Q All right. If you can go back to 6 Exhibit 2 real fast, which is the considered list 7 that was provided to us with your report? 8 A Yeah. 9 Q And tell me when you got that? 10 A I have that. 11 Q You'll see that number -- number seven is 12 an article in the BMJ from Hviid? 13 A Yeah. 14 Q H-v-i-i-d 2020; right? 15 A Hviid. 16 Q Yes? 17 A Yes. Hviid. 18 Q And obviously we talked about the 19 Arana 2017 article at number three; right? 20 A Yes. 21 Q You also have an article here, number 22 eight, Cameron, which is related to monitoring in 23 Scotland; do you see that? 24 A I see that. 25 Q And you have, for example, number 26,</p>	<p style="text-align: right;">Page 289</p> <p>1 Q Yes, Katherine E.? 2 A Is that. 3 Q Number twenty-three? 4 A I think that's listed here. 5 Q Is it number 23? 6 A Probably. I would have to double-check 7 that the -- the -- the title is the same. 8 Q And Gee 2017, is that number 25? 9 A I don't know if that is it. 10 Q Okay. All right. As part of the 11 80 hours or so working on this case, do you think 12 you read every one of the articles on Exhibit 2? 13 A I did not read all of those articles, no. 14 Q Do you agree that vaccines represent one 15 of the greatest achievements in medicine in public 16 health? 17 A Yes. Together with antibiotics and 18 anesthesia and sanitation. 19 Q Do you agree that vaccine programs have 20 significantly decreased the number of cases of 21 vaccine-preventable diseases over the past century? 22 A More than that -- longer than that, yes. 23 Q Do you believe that vaccines are a vital 24 medical invention allowing people to obtain immunity 25 without the risk that comes from getting sick?</p>

<p style="text-align: right;">Page 290</p> <p>1 A Yes.</p> <p>2 Q And regardless of what anybody wants to</p> <p>3 think about the COVID pandemic, you would agree that</p> <p>4 the development of several vaccines against COVID</p> <p>5 infection is one of the few scientific success</p> <p>6 stories of the COVID pandemic; right?</p> <p>7 MR. BAUM: Objection. Irrelevant</p> <p>8 and speculative.</p> <p>9 A I think that the vaccines saved the lives</p> <p>10 of a lot of older people in 2021.</p> <p>11 (Whereupon, Exhibit MK 37, New</p> <p>12 England Journal of Medicine article</p> <p>13 from Salmon, was marked for</p> <p>14 identification.)</p> <p>15 MR. TOMASELLI: I'm just curious.</p> <p>16 BY MR. TOMASELLI:</p> <p>17 Q I'm handing you what I've marked as</p> <p>18 Exhibit 37, which is a publication in New Eng- --</p> <p>19 New England Journal of Medicine from Salmon,</p> <p>20 S-a-l-m-o-n, and Orenstein and others; do you see</p> <p>21 that?</p> <p>22 A Yes, it came out this summer.</p> <p>23 Q Yeah. I'm just curious why -- why you</p> <p>24 had this on your materials reviewed list?</p> <p>25 A Don't ask me, ask my attorney.</p>	<p style="text-align: right;">Page 292</p> <p>1 probably not going to be more than that.</p> <p>2 Maybe one minute.</p> <p>3 MR. TOMASELLI: Okay. Because I --</p> <p>4 MR. BAUM: You want to get out of</p> <p>5 here.</p> <p>6 MR. TOMASELLI: Yeah.</p> <p>7 THE VIDEOGRAPHER: The time is</p> <p>8 3:55 p.m. and we are off the record.</p> <p>9 (Whereupon, there was a recess taken</p> <p>10 from 3:55 p.m. to 3:58 p.m.)</p> <p>11 MR. BAUM: We have no questions.</p> <p>12 MR. TOMASELLI: Thank you, again,</p> <p>13 Dr. Kulldorff, for indulging me with my</p> <p>14 questions and I hope you have a great</p> <p>15 rest of your day.</p> <p>16 THE WITNESS: Thank you. And enjoy</p> <p>17 your trip back.</p> <p>18 MR. TOMASELLI: Thank you.</p> <p>19 THE WITNESS: Enjoy your daughter.</p> <p>20 MR. TOMASELLI: Thank you.</p> <p>21 THE WITNESS: And I hope they enjoy</p> <p>22 you when you come home also.</p> <p>23 MR. TOMASELLI: Thank you.</p> <p>24 THE WITNESS: Thank you for doing</p> <p>25 the deposition in a polite and friendly</p>
<p style="text-align: right;">Page 291</p> <p>1 Q Okay. In terms of the second page, the</p> <p>2 chart of understanding the biologic mechanisms of</p> <p>3 vaccine adverse reactions; do you see that?</p> <p>4 A Yup.</p> <p>5 Q You didn't -- you didn't have any --</p> <p>6 you're -- you're not citing this for any particular</p> <p>7 reason that you can recall?</p> <p>8 A I did not use this one for my report.</p> <p>9 Q Okay. And at least in terms of the table</p> <p>10 here, there's no vaccine adverse reaction in it</p> <p>11 related to Gardasil; true?</p> <p>12 A There's no Gardasil vaccine there in that</p> <p>13 table.</p> <p>14 Q And there are vaccine adverse reactions</p> <p>15 that are detailed after the marketing of Gardasil;</p> <p>16 correct?</p> <p>17 A Yes. The last one I listed here is from</p> <p>18 2024.</p> <p>19 Q Okay.</p> <p>20 MR. TOMASELLI: Dr. Kulldorff, I</p> <p>21 appreciate your indulgence of my</p> <p>22 questions and I'll pass the witness.</p> <p>23 THE WITNESS: Okay.</p> <p>24 MR. BAUM: Let me take a -- like, a</p> <p>25 five-minute break and come back but I'm</p>	<p style="text-align: right;">Page 293</p> <p>1 manner.</p> <p>2 MR. TOMASELLI: You're welcome.</p> <p>3 THE WITNESS: It's always fun to</p> <p>4 talk about science.</p> <p>5 MR. TOMASELLI: Indeed.</p> <p>6 THE WITNESS: It's sort of a</p> <p>7 different way of doing it than with my</p> <p>8 scientific colleagues, but science is so</p> <p>9 much fun.</p> <p>10 MR. TOMASELLI: I agree. Thank you,</p> <p>11 sir.</p> <p>12 (Whereupon, there was a discussion</p> <p>13 off the record.)</p> <p>14 COURT REPORTER: Attorney Baum, can</p> <p>15 I ask if you would like to order a copy</p> <p>16 of the transcript?</p> <p>17 MR. BAUM: Yeah. Could I get a</p> <p>18 rough?</p> <p>19 COURT REPORTER: Sure thing.</p> <p>20 MR. BAUM: I don't need the final</p> <p>21 rushed but just the rough.</p> <p>22 COURT REPORTER: Sure thing.</p> <p>23 MS. VALOFF: And I would like a copy</p> <p>24 of the transcript, please.</p> <p>25 COURT REPORTER: Certainly. Thank</p>

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	<p style="text-align: right;">Page 294</p> <p>you.</p> <p>Is there anyone else on Zoom? (Thereupon, the deposition was concluded at 4:01 p.m. EDT.)</p> <p>C E R T I F I C A T E</p> <p>I hereby certify that I am a Notary Public, in and for the State of Connecticut, duly commissioned and qualified to administer oaths.</p> <p>I further certify that the deponent named in the foregoing deposition was by me duly sworn, and thereupon testified as appears in the foregoing deposition; that said deposition was taken by me stenographically in the presence of counsel and reduced to typewriting under my direction, and the foregoing is a true and accurate transcript of the testimony.</p> <p>I further certify that I am neither of counsel nor attorney to any of the parties to said suit, nor am I an employee of any party to said suit, nor of any counsel in said suit, nor am I interested in the outcome of said cause.</p> <p>Witness my hand and seal as Notary Public this 27th day of October, 2024.</p> <p></p> <hr/> <p>Clifford Edwards Connecticut Notary Public No. SNPC.0129714 My commission expires: 9/30/2026</p>
	<p style="text-align: right;">Page 295</p> <p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>

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